HORIBA
Medical

ABX Micros 60

Hematology Analyzer

User Manual

Ref: RAB042IEN

ABX Micros 60

User manual

P/n: RAB042IEN

IVD CE

HORIBA ABX SAS
B.P. 7290
34184 MONTPELLIER Cedex 4 - FRANCE

1. Revisions

Tab. 1: User Manual revisions

Index	Technical note	Software revision	Modifications	Section	Date
Ba	RAH911AA	V1.4		All	05/23/02
Bb	RAH911AA	V1.4		1,3,6	11/04/02
Ca	RAH939AA	V1.6		All	12/10/02
Cb	ECR1354	V1.6	UL correction	1	01/09/03
Da	RAH986AA	V1.6	CE IVD Norms	Intro, 1	16/09/03
EEN	RAN153AA	V1.6	**HORIBA Medical**	All	09/03/05
FEN	RAN252AA	V1.7.0	see 10.1. Corrections associated to V1.7.0. Software version, page Introduction-18	All	15/06/06
GEN	RAN153DA	V1.7.0	see "10.2. Corrections associated to new version, page 19"	All	04/03/08
HEN	-	-	-	-	-
IEN	ECR4015	V1.7.0	New cTUVus certification	Intro, 1	09/07/09

- This document applies to the latest software listed and higher versions.
- When a subsequent software version changes the information in this document, a new electronic issue (CD-ROM and/or online help) is released and supplied by **HORIBA Medical**.
- To update a paper document, please contact your local **HORIBA Medical** representative.

HORIBA ABX SAS
B.P. 7290
34184 MONTPELLIER Cedex 04 - FRANCE

Tel: +33 (0)4 67 14 15 16
Fax: +33 (0)4 67 14 15 17

1.1. Declaration of conformity

- Latest version of the CE declaration of conformity for this instrument is available on www.horiba.com

1.2. Notice of liability

The information in this manual is distributed on an "As Is" basis, without warranty. While every precaution has been taken in the preparation of this manual, **HORIBA Medical** will not assume any liability to any persons or entities with respect to loss or damage, caused or alleged to be caused directly or indirectly by not following the instructions contained in this manual, or by using the computer software and hardware products described herein in a manner inconsistent with our product labeling.

1.3. Trademarks

Product names mentioned within this publication may be trademarks or registered trademarks of their respective owners.

1.4. Copyright 2009 HORIBA ABX SAS

All rights reserved. No part of this book may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of **HORIBA Medical**.

1.5. Potential hazards

To alert the operator of potentially hazardous conditions, one of the bold captioned headings which are described below is provided wherever necessary throughout this text.

WARNING: Flags a procedure that if not followed properly, can prove to be extremely hazardous to either the operator or the environment or both.

CAUTION: Emphasizes an operating procedure that must be followed to avoid possible damage to the instrument or erroneous test results.

NOTA: Emphasizes important information especially helpful to the operator before, during or after a specific operational function.

2. Warning and precautions

- Work safety reliability and general characteristics are guaranteed by **HORIBA Medical** under the following conditions:

  - User manual must be enterely read and personnel trained by **HORIBA Medical** before attempting to operate instrument.
  - The user always operates with full knowledge and appreciation of instrument warnings, alarms and flags.
  - Always refer to labeling and **HORIBA Medical** instructions in order to avoid to compromise system integrity.

- The instrument must be operated as instructed in the user manual. Any other use might compromise system integrity and might be hazardous for the operator.

- **The reagents and accessories stipulated by HORIBA Medical have been validated in accordance with the European Directive for in-vitro medical devices (98/79/CE).**
- **The use of any other reagents and accessories may place at risk the performance of the instrument, engaging the users responsability. In this case, HORIBA Medical takes no responsability for the device nor for the results rendered.**
- **Disposal gloves, eyes protection and lab coat must be worn by the operator.**
- **Local or national regulations must be applied in all the operations.**
- **Portable/mobile telephones should not be used in proximity of the instrument.**
- **All peripheral devices should comply with relevant standards.**

2.1. Limited guarantee

The duration of guarantee is stipulated in the sales conditions associated with the purchase of this instrument. To validate the guarantee, ensure the following is adhered to:

1- The system is operated under the instructions of this manual.
2- Only software or hardware specified by **HORIBA Medical** is installed on the instrument. This software must be the original copyrighted version.
3- Services and repairs are provided by a **HORIBA Medical** authorized technician, using only **HORIBA Medical** approved spare parts.
4- The electrical supply of the laboratory adheres to national or international regulations.
5- Specimens are collected and stored in normal conditions.
6- Reagents used are those specified in this user manual.
7- Proper tools are used when maintenance or troubleshooting operations are performed.

If this instrument has been supplied to you by anyone other than HORIBA Medical or an authorised representative, HORIBA Medical cannot guarantee this product in terms of specification, latest revision and latest documentation. Further information may be obtained from your authorised representative.

2.2. Safety Precautions

Electronic and moving parts:

The following parts must not be handled or checked by the user:
- Electrical power supply.
- Electronic circuit boards.

- **Operator injury may occur from an electric shock. Electronic components can shock and injure the user. Do not tamper with the instrument and do not remove any components (covers, doors, panels and so on) unless otherwise instructed within this document.**
- **Moving parts: It is strictly forbidden to disable sensors as it may cause operator injuries. Protection covers must not be opened during instrument operations.**
- **The battery may explode if it is not replaced correctly! Replace only with the same or equivalent type recommanded by the manufacturer. Dispose of used batteries according to the manufacturer's instructions.**

2.3. Biological risks

Consider all specimens, reagents, calibrators, controls, etc... that contain human blood or serum as potentially infectious ! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other bio-safety practices as specified in OSHA Blood Borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent bio-safety procedures.

HORIBA Medical uses disinfectant product for instrument decontamination and highly recommends it to decontaminate your instrument (See Section 6, 1.1.3. General Cleaning of the Instrument, page 6-3)

3. Working conditions

3.1. Environment

- The operation of the ABX **Micros 60** should be restricted to indoor location use only. This instrument is operational at an altitude of maximum 2000 meters (6000 feet).
- The ABX **Micros 60** is designed for safety from voltages surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2 (IEC 61010-1).

Please contact your local HORIBA Medical representative if use conditions do not comply with the recommended specifications.

3.2. Location

- The ABX **Micros 60** should be placed on a clean and leveled table or workbench.
- Please note that the ABX **Micros 60**, printer and reagents weigh approximately 30 kilograms (66 lbs).
- Avoid exposure to sunlight.

- Place your instrument where it is not exposed to water or vapor.
- Place your instrument where it is free from vibration or shock
- Place your instrument where an independent power receptacle can be used.
- Use a receptacle different from the one used by a device that easily generate noise such as a centrifuge, etc...
- Provide a space of at least 20 cm (8 inches) at the back of the instrument for arranging the power cable and tubings.

The power switch and input voltage supply connection should always be accessible. When positioning the system for operational use, leave the required amount of space for easy accessibility to these items

3.3. Grounding

Proper grounding is required when installing the system. Check the wall outlet ground (earth) for proper grounding to the facilities electrical ground. If you are unsure of the outlet grounding, contact your facilities engineer to verify the proper outlet ground.

3.4. Humidity/temperature conditions

The ABX Micros 60 must operate between temperatures of 18 to 32°C (65 to 90°F). Maximum relative humidity 80% for temperatures up to 31°C (88°F). If it is stored at a temperature less than 10°C (50°F), the instrument should stand for 1 hour at the correct room temperature before use.

3.5. Electromagnetic environment check

- The ABX Micros 60 has been designed to produce less than the accepted level of electromagnetic interference in order to operate in conformity with its destination, allowing the correct operation of other instruments also in conformity with their destination.
- In case of suspected electromagnetic noise, check that the instrument has not been placed in the proximity of electromagnetic fields or short wave emissions, (Radar, X-rays, Scanners, Cell phones, etc.).

3.6. Environmental protection

3.6.1. Disposable used accessories and consumables:

Must be collected by a laboratory specialized in elimination and recycling of this kind of material according to the local legislation.

3.6.2. ABX Micros 60 instrument disposal :

It should be disposed of, in accordance with local legislation, and should be treated as being contaminated with blood. The appropriate biological precautions should be taken.

If any doubt, please contact your HORIBA Medical representative service department.

▼ European Legislation

In accordance with the European Directive (2002/96/CE, known also as W.E.E.E) instruments having the above symbol, and sold into a European country by **HORIBA Medical** or an authorised representative must be disposed of and recycled correctly at the end of its useful life.

Due to the local changing regulations in each country, please contact your local representative for detailed and upto date information on how to appropriately dispose of the instrument.

3.7. Transportation and storage conditions

◆ Condition for storage and transportation: Temperature from -20°C to +50°C

Prior to the shipping of an instrument by transporter, whatever the destination, an external decontamination of the instrument must be carried out.

4. Graphics and symbols

	Switch off position		Switch on position
	Alternating current		Manufacturer
	In Vitro Diagnostic Medical Device		This product conforms to the EEC Standards and Directives named in the Declaration of Conformity.
	Caution, consult accompanying documents		Biological risks
	Reagent		Up
	Fragile, handle with care		Keep dry
	Do not stack		Temperature limitation
	Batch code		Catalogue number
	Use by		Consult instructions for use
	Calibrator		Control
	Content		Ground
	Packaging recycling mark		This product should be disposed of and recycled at the end of the useful life in accordance with the WEEE Directive (2002/96/CE)
	Notice of environment-friendly use period		

All graphics including screens and printout, photographs are for illustrations purposes only and are not contractual.

5. Labels

5.1. Main power label

In order to replace the 2x1A Fuses located under the power plug connection on the back of the analyzer, carry out the following procedure:

- Do not remove the instrument protection cover.
- Power OFF the analyzer.
- Disconnect the main power cable from the back power cord receptacle on the analyzer.
- Pull the little flap marked «250V fuse».
- Remove the fuses from their holding receptacle
- Use only fuses having the following characteristics: 1A TT 250V

5.2. Input/Output Label

Waste: Connect the waste output line to the (Waste position) fitting. Note the Waste label for Waste output «Only»
Diluent: Connect the Diluent input line to the (Diluent position) fitting. Note the Diluent label for Diluent input «Only»
Lyse: Connect the Clear tubing marked with a «MINILYSE» label to a straw and place it into the Lyse reagent container.
Miniclean: Connect the Blue tubing marked with a «MINICLEAN» label to a straw and place it into the Miniclean reagent container.
RS-232 output connection: Used only by **HORIBA Medical** qualified Engineers.
Printer connection: Do not connect any printer which has not been recommended by a **HORIBA Medical** qualified Engineer.

5.3. «Biological risks» label

This label is located on the left side cover

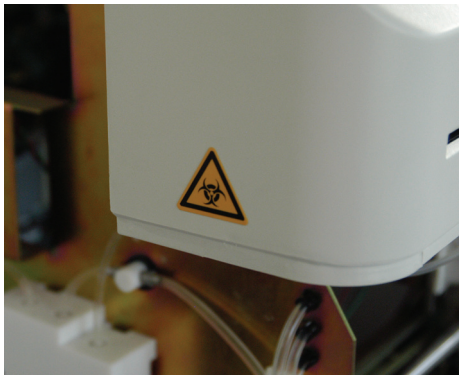


Fig. 1: Biological risks

Consider all specimens, reagents, calibrators, controls, etc... that contain human blood or serum as potentially infectious ! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other bio-safety practices as specified in OSHA Blood Borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent bio-safety procedures.

5.4. Internal label

This label is located on the WBC chamber cover (main covers must be opened to reach it)

Fig. 2: ESD label

Electrostatic Sensitive Device (ESD).
The reagent and chambers are susceptible to cause ESD damage to the instrument motherboard when they are handled without ESD safe handling tools.
Make contact with the instrument ground (cover screw for example) before proceeding on the chambers in order to prevent electrostatic discharges

5.5. Identification Label

Fig. 3: Identification label

6. Intended use

The ABX **Micros 60** OS/OT is a fully automated (Microprocessor controlled) Hematology analyzer used for in-vitro diagnostics testing of Whole Blood specimens and Whole Blood component concentrates.

Important: When analyzing Whole Blood component concentrates, you must consider the Linear Range of the component parameter and its associated parameters if any. These concentrates may prematurely pollute the counting aperture when analyzing them. It is suggested that you perform 3 Backflushes and/or a Concentrated Cleaning after analyzing the concentrates.

The ABX **Micros 60** OS/OT is available in 5, 8, 16, and 18 parameters. These parameters are noted according to the system setup (See Section 1, 1.1. Parameters, page 1-3)

The Rate of determination is approximately 60 samples per hour in the optimum configuration. The system is totally automated,including an internal dilution system, and a Graphic printer for recording all test results including flags and graphics.

7. Presentation

The ABX **Micros 60**, which is small in size, has 8 main parts.
1- The Electrical supply.
2- The Electronic Main board.
3- The Dilution Pneumatics.
4- The Control panel, including a key pad and LCD screen.
5- A Reagent compartment.

6- A Printer that prints out results and Distribution curves.
7- A Smart Card Reader (optional) for Quality Control result records and Patient result records.
8- A Barcode reader (optional) for a direct entry of the Alphanumerical identifications.

ABX **Micros 60** **Models Available:**

This instrument is available in the following different models:
- TheABX **Micros 60**-0T: This model is an «Open Tube» unit «Without» a Smart Card reader. The operator must remove the cap from the blood collection tube before analyzing any sample.
- The ABX **Micros 60**-0S: This model is an «Open Tube» unit «With» a Smart Card reader. The Smart Card reader gives the operator the ability to record results and perform automated Quality Control. The operator must remove the cap from the blood collection tube before analyzing any sample.

0T and 0S are indicated in the instrument serial number that identifies the unit and model.

8. Installation

An **HORIBA Medical** representative will install your instrument, software, and printer.

8.1. Package contents

A thorough inspection is carried out on the ABX **Micros 60** before sending it. We, nevertheless, recommend checking the total system as soon as it is received to report any anomalies to the carrier.
Verify that all of the parts from the package list are present:

The ABX **Micros 60**-0S/0T boxes contain the following parts :
- Instrument
- Printer
- User manual CDROM: RAX056A
- Reagents, controls & calibrators CD ROM: RAX055A
- Daily guide : RAB180
- Power cable (european) : DAC011A or power cable (US) : DAC012A
- Installation kit (Bottle or Pack)

8.1.1. «Bottle» Installation kit

The ABX **Micros 60**-0T «bottle» installation kit (XEA 314 B) includes :

Tab. 2: Bottle installation kit

DESIGNATION	PART NUMBER	QTY
Reagent straw L=270 mm	XEA017A	3
Sampling needle	GBC069AS	1
Diluent/Waste male connector	EAC019A	2
Cristal tube 3x6	EAE011A	4
O' ring 6x1.5	FAA036A	1
O' ring 1.4x1.25	FAA0053A	2
Rubber stopper 2 holes	FBL001A	1
Reagent bottle stopper	XDA566A	2

Tab. 2: Bottle installation kit

DESIGNATION	PART NUMBER	QTY
Common installation kit	XEA312B	1

8.1.2. «Pack» installation kit

The ABX Micros 60-OT «pack» installation kit (XEA 332 B) includes :

Tab. 3: Pack installation kit

DESIGNATION	PART NUMBER	QTY
Sampling needle MICROS 60-CT	GBC069AS	1
O' ring 6x1.5	FAA036A	2
O'ring 0.74x1.02	FAA053A	2
Common installation kit	XEA312B	1

8.2. Reagent connections

(See Section 6, 1.2. Reagent connections, page 6-4)

9. User manual contents

Introduction Introduction-2
Warning and precautions Introduction-4
Working conditions Introduction-5
Graphics and symbols Introduction-8
Labels Introduction-9
Intended use Introduction-11
Presentation Introduction-11
Installation Introduction-12
User manual contents Introduction-15
User manual modifications Introduction-16

Section 1. Specifications 1-1
Technical Specifications (V1.7.0) 1-3
Physical Specifications 1-6
Summary of Performance Data 1-8
Limitations 1-13
Reagent Specifications 1-19
Reagent Consumption 1-20
Waste Handling Procedure 1-20

Section 3. Workflow 3-1
Startup checks 3-2
Daily Quality Control & Calibration verification 3-5
Sample selection and identification 3-6
Running Samples 3-8
Results 3-10
Flags 3-15

Section 2. Description & technology 2-1
Description 2-2
Technology 2-3

Section 4. Quality Assurance 4-1
Quality Control 4-2
Calibration 4-11

Section 5. Setup 5-1
Setup overview 5-2
Results Options 5-3
Laboratory Limits 5-7
Special Functions 5-10
Date and Time 5-15
Host Computer Options 5-16
Barcode Setup 5-17
Memory Card 5-17

Section 6. Maintenance & Troubleshooting 6-1
Maintenance 6-2
Troubleshooting 6-18
Menu/Overview 6-25

10. User manual modifications

10.1. Corrections associated to V1.7.0. Software version

V1.7.0 Version # update Introduction-2

declaration of conformity removed..... Introduction-3

weee directive Introduction-8

Identification Label modified..... Introduction-11

PRP specification removed..... Introduction-11

Installation procedure removed (technical manual) Introduction-13

Package content modification Introduction-13

addition alphalyse 360..... Chap 1-5

Link CD Reagent leaflets..... Chap 1-5

Heat Output addition..... Chap 1-6

CEIvd approved reagents correction ..... Chap 1-19

Addition CD ROM reagent leaflets RAX055 ..... Chap 1-19

Startup Background limits management on HGB..... Chap 3-3

2SD (standard deviation) replaced by SD in QC ..... Chap 4-9

Calibration general recommendations addition ..... Chap 4-11

10.2. Corrections associated to new version

Updated documents information ....Introduction - 2

Copyright modified and updated..... ..... Introduction - 3

New warning about reagent replacement..... .....Chap. I - 20

New values of reagent consumption ....Chap. I - 20

New warning about risk of wastes projections..... ..... Chap. III - 2

Limits of CV on Control blood added..... .....Chap. IV - 8

Contents

1. Technical Specifications (V1.7.0) 1-3
1.1. Parameters 1-3
1.2. Throughput Analysis 1-4
1.3. Memory Capacity (Smart Cards) 1-5
1.4. Statistics and Quality Control 1-5
1.5. Reagents 1-5
1.6. Calibration 1-5
1.7. Measurements and Computation 1-5
1.8. Outputs 1-5
1.9. Display 1-6
1.10. Barcode Reader Options 1-6
2. Physical Specifications 1-6
2.1. Power Requirements 1-6
2.2. Operating Temperature/Humidity 1-6
2.3. Dimensions and Weight 1-6
2.4. Wastes 1-6
2.5. Minimum Sample Volume 1-6
2.6. Dilution Ratios 1-7
2.7. Counting Aperture Diameter 1-7
2.8. Hemoglobin Measurement 1-7
3. Summary of Performance Data 1-8
3.1. Precision (Reproducibility)* 1-8
3.2. Precision Claims* 1-9
3.3. Precision (Repeatability) 1-10
3.4. Linearity* 1-10
3.5. Carry-over 1-11
3.6. Normal Ranges 1-11
3.7. Accuracy 1-12
3.8. Leucocytes Differential count 1-12
3.9. Sample stability study 1-12
4. Limitations 1-13
4.1. Maintenance 1-13
4.2. Blood Specimens 1-13
4.2.1. Sample collection and mixing 1-13
4.2.2. Sample Stability 1-13
4.2.3. Anti-coagulants and their effects (on whole blood) 1-14
4.3. Known Interfering Substances 1-14
4.3.1. HCT (Hematocrit) 1-14
4.3.2. RBC Red Blood Cells (Erythrocytes) 1-14
4.3.3. WBC White Blood Cells (Leukocytes) 1-15
4.3.4. HGB (Hemoglobin) 1-16
4.3.5. MCV (Mean Corpuscular Volume) 1-16
4.3.6. MCH (Mean Corpuscular Hemoglobin) 1-16
4.3.7. MCHC (Mean Corpuscular Hemoglobin Concentration) 1-16
4.3.8. RDW (Red cell Distribution Width) 1-16
4.3.9. PLT (Platelets) 1-17
4.3.10. MPV (Mean Platelet Volume) 1-17
4.3.11. LYM # (Lymphocyte count Absolute Number) 1-18
4.3.12. LYM % (Lymphocyte Percentage) 1-18
4.3.13. MON # (Monocyte count Absolute Number) 1-18

4.3.14. MON % (Monocyte Percentage) 1-18
4.3.15. GRA # (Granulocyte count Absolute Number) 1-18
4.3.16. GRA % (Granulocyte Percentage) 1-18
5. Reagent Specifications 1-19
6. Reagent Consumption 1-20
7. Waste Handling Procedure 1-20

1. Technical Specifications (V1.7.0)

- WBC, RBC, and PLT Histograms
- Quantitative Flags
- Parameter selection by choice of Software

Note: The ABX Micros 60 performs automated blood counts and requires no manual operations for aspirating blood, dilutions, measuring, calculations, print-outs, and computer transfer of data. The parameters are given according to the Internal Setup

1.1. Parameters

Tab.1-1: ABX Micros 60 - 5 parameters

5 parameters	
WBC	White Blood Cells
RBC	Red Blood Cells
HGB	Hemoglobin
HCT	Hematocrit
MPV	Mean Platelet Volume
RBC Distribution Curve	

Tab.1-2: ABX Micros 60 - 8 parameters

8 parameters	
WBC	White blood cells
RBC	Red blood cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
PLT	Platelets
RBC and PLT Distribution Curves	

Tab.1-3: ABX Micros 60 - 16 parameters

16 parameters	
WBC	White blood cells
LYM %	Lymphocyte Percentage
LYM #	Lymphocyte Absolute number
MON %	Monocyte Percentage
MON #	Monocyte Absolute number
GRA %	Granulocyte Percentage
GRA #	Granulocyte Absolute number

Tab.1-3: ABX Micros 60 - 16 parameters

16 parameters	
RBC	Red blood cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red cell Distribution Width
PLT	Platelets
MPV	Mean Platelet Volume
WBC, RBC, and PLT Distribution Curves	

Tab.1-4: ABX Micros 60 - 18 parameters

18 Parameters	
WBC	White blood cells
LYM %	Lymphocyte Percentage
LYM #	Lymphocyte Absolute number
MON %	Monocyte Percentage
MON #	Monocyte Absolute number
GRA %	Granulocyte Percentage
GRA #	Granulocyte Absolute number
RBC	Red blood cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red cell Distribution Width
PLT	Platelets
MPV	Mean Platelet Volume
PDW	Platelet Distribution Width
PCT	Plateletcrit
WBC, RBC, and PLT Distribution Curves	

PCT and PDW have not been established as indications for this product, in the United States. The use of PCT and PDW should be restricted to Research Use Only.

1.2. Throughput Analysis

- Approximately 60 Samples/ hour.

1.3. Memory Capacity (*Smart Cards*)

- Last sample «ONLY» .....Internal Memory capacity
- 60 samples .....Memory Smart Card option
- 99 samples .....Quality Control Smart Card option

1.4. Statistics and Quality Control

- Extended Quality Control package (Optional).
- Quality Control Smart Card option.

1.5. Reagents

3 Reagents or 1 Pack of Reagents

- Diluent: .....ABX MINIDIL LMG (10L)
- Cleaner: .....ABX MINICLEAN (1L)
- Lyse: .....ABX MINILYSE (1L) or
  .....ABX MINILYSE LMG (1L) or
  .....ABX ALPHALYSE 360 (0.36L)

- all reagents: .....ABX MINIPACK LMG (4.2L)

The CD ROM RAX055 delivered with your instrument provides Reagents, Controls and Calibrators leaflets/msds. Latest versions of these documents are available on www.horiba.com

1.6. Calibration

- Automatic Calibration procedure.
- Direct entering of Calibration Coefficients.

1.7. Measurements and Computation

- Impedance change for WBC, RBC, PLT
- Spectrophotometry for HGB
- Impedance change for LYM%, MON%, GRA%
- Computation from stored Data that was directly measured for MCV, MCH, MCHC, RDW, MPV, LYM#, MON#, GRA#

1.8. Outputs

- Hard Copy printing
- External output (RS232)

1.9. Display

- LCD Screen: ..... 2 Lines of 40 characters, backlighted

1.10. Barcode Reader Options

- EAN 8, EAN 13, C 39, C 128, ITF (2of5), CODABAR, STF
- C 93 with or without Checksum.

2. Physical Specifications

2.1. Power Requirements

- Power supply: ..... 100V-240V (+/- 10%)
  ..... 50-60Hz
- Power Consumption:..... Maximum: 65W
  ..... In use: 65W
  ..... Stand-by mode: 35W
- Heat output..... 197Kj/h (187BTU/h)

2.2. Operating Temperature/Humidity

- 18 to 32°C (65 to 90°F)
- Maximum relative Humidity, 80% for temperatures up to 31°C (88°F) decreasing linearly to 50% relative humidity at 40°C (104°F).
- Avoid exposure to direct sunlight.
- Avoid exposure to air conditioning and or heating ducts.

2.3. Dimensions and Weight

- Height: ..... Approximately 440mm (16.5 inches)
- Width: ..... Approximately 360mm (14.2 inches)
- Depth: ..... Approximately 330mm (12.6 inches)
- Weight: ..... Approximately 14Kgs (31 lbs)

2.4. Wastes

- Automatic disposal.
- Waste handling according to Local/National regulations.

2.5. Minimum Sample Volume

- Minimum blood sample requirement: 50µl
- Analyzer sample volume:..... ..... 10µl

2.6. Dilution Ratios

- WBC: .....Approximately 1/250
- RBC/PLT: .....Approximately 1/15000

2.7. Counting Aperture Diameter

- WBC: 80µm
- RBC: 50µm

2.8. Hemoglobin Measurement

- Performed in the WBC/HGB Chamber
- Light source: LED (Light Emiting Diode) at wavelength 550nm

3. Summary of Performance Data

3.1. Precision (Reproducibility)*

The ABX Micros 60 was initially calibrated with Minocal Calibrator (Lot N° MCAL 325 Expiry Date: 11-05-2002).

Three levels of ABX Minotrol 16 control material (Lot N°: M243) were run in duplicate twice daily for 20 days. The results were used to quantify within run precision, SD of the run means, SD of the daily means, and the Total Imprecision with the NCCLS EP-5 Guidelines.

Tab.1-5:

Parameter	MINOTROL 16 Control	Within Run SD	SD of Runs Means	SD of Daily Means	Total imprecision (SD)
WBC	M243 High	0.23	0.20	0.19	0.29
	M243 Normal	0.10	0.08	0.11	0.14
	M243 Low	0.06	0.03	0.04	0.06
RBC	M243 High	0.05	0.04	0.04	0.06
	M243 Normal	0.05	0.04	0.04	0.06
	M243 Low	0.04	0.03	0.03	0.04
HGB	M243 High	0.31	0.23	0.40	0.49
	M243 Normal	0.12	0.16	0.43	0.45
	M243 Low	0.09	0.22	0.29	0.33
HCT	M243 High	0.52	0.79	0.96	1.17
	M243 Normal	0.56	0.51	0.74	0.91
	M243 Low	0.26	0.26	0.32	0.42
PLT	M243 High	13.71	6.49	9.07	14.04
	M243 Normal	9.17	7.23	5.87	10.13
	M243 Low	5.83	3.78	3.69	4.97

Tab.1-6:

Parameter	MINOTROL 16 Control	Within run CV%	CV% of run means	CV% of Daily means	Total imprecision (CV%)
WBC	M243 High	1.19	1.01	0.96	1.46
	M243 Normal	1.39	1.11	1.46	1.93
	M243 Low	3.06	1.68	1.93	3.13
RBC	M243 High	0.9	0.62	0.78	1.1
	M243 Normal	1.02	0.88	0.8	1.24
	M243 Low	1.46	1.07	1.15	1.72
HGB	M243 High	1.72	1.28	2.23	2.7
	M243 Normal	0.85	1.17	3.17	3.33
	M243 Low	1.49	3.5	4.65	5.37
HCT	M243 High	1.06	1.62	1.96	2.39
	M243 Normal	1.51	1.38	2	2.47
	M243 Low	1.6	1.6	1.96	2.53
PLT	M243 High	2.89	1.37	1.91	2.96
	M243 Normal	9.17	7.23	5.87	10.13
	M243 Low	5.14	6.87	6.70	9.04

Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guidelines, NCCLS document EP-5 (ISBN 1-56238-145-8) 1999

*Source 510K submission # K030799

3.2. Precision Claims*

Tab.1-7:

Parameters	%CV	Nominal Values
WBC	<2.5%	10.0 x 10^3 /µL
RBC	<2.0%	5 x 10^6 /µL
HGB	<1.5%	15 g /dL
HCT	<2.0%	45 %
PLT	<5.0%	300 x 10^3 /µL

*Source 510K submission # K030799

3.3. Precision (Repeatability)

Based on 20 consecutive samplings from 1 Fresh Normal Whole Blood, without any alarms.

Tab.1-8:

Precision Table: N = 20 Parameters	%CV	Test Level
WBC	<2.5%	10.0 x 10^3 /µL
RBC	<2.0%	5 x 10^6 /µL
HGB	<1.5%	15 g /dL
HCT	<2.0%	45 %
PLT	<5.0%	300 x 10^3 /µL

3.4. Linearity*

◆**Linearity range**: The Manufacturer's tested linearity zone of the instrument using linearity kits and/or human blood.

◆**Linearity limits**: Maximum and minimum values within the instrument returns no dilution alarm.

◆**Visible Range**: Range values given by the instrument. These values (above linearity limits) are given as an indication. They are given associated with a «D» flag. This Visible range is outside Manufacturer's range.

◆**Linearity Kits:** Linearity was tested using available «Low Range» and «Full Range» Linearity Test kits. The Test kits were analyzed and data was computed according to the Manufacturer's instructions.

◆**Human Blood**: Linearity was also obtained on human blood, using a minimum of 5 dilution point. The results of this study are as followed

Tab.1-9:

Parameters	Linearity Range	Linearity limits	Visible Range	Error limit (Which ever is greater)	
WBC (10^3/mm^3)	0.5 - 122	0 - 100	100 - 150	± 0.3	± 5 %
RBC (10^6/mm^3)	0.2 - 8.7	0 - 8	8 - 18	± 0.07	± 3 %
PLT (10^3/mm^3) (**A**)	10 - 2327	0 - 2200	2200 - 6000	± 10	± 10%
PLT (10^3/mm^3) (**B**)	25 - 4990	0 - 4000	4000 - 6000	± 10	± 10%
HGB (g/dL)	2.0 - 27	0 - 26	26 - 30	± 0.3	± 3 %
HCT (%)	1.8 - 82.3	0 - 80	80 - 90	± 2.0	± 3 %

*Source 510K submission # K030799

A: for HGB> 2 g/dL and RBC>0.5x10^6/mm^3
B: for HGB< 2 g/dL and RBC>0.5x10^6/mm^3

3.5. Carry-over

Carry-over was tested by analyzing samples with «High Concentrations» of WBC's, RBC's, HGB, and PLT's. Each sample was analyzed in triplicate, followed by 3 background cycles. The % Carry-over is calculated by using the following formula:

Carry-over = (Background1 - Background3)/(Sample3 - Background3) X 100

Tab.1-10:

Parameters units	WBC ($10^3/mm^3$)	RBC ($10^6/mm^3$)	HGB (g/dL)	PLT ($10^3/mm^3$)
Blood count Level	63.0	7.58	23.4	988
% Carry-over (Actual)	0.3	0.00	0.0	0.0
% Carry-over (Claimed)	< 0.5%	<0.5%	<0.5%	<0.5%

3.6. Normal Ranges

These Normal ranges were established from a study performed in Somerville, NJ. (U.S.A.) This study encompasses the central 95% of the values, in the distribution of 43 Normal, Healthy, and Drug Free individuals. These Ranges are as followed:

Tab.1-11:

Parameters		Male (N=21)	Female (N=22)
WBC	($10^3/mm^3$)	4.7 - 9.6	4.9 - 12.3
Lymphocytes	(%)	23 - 47	19 - 41
Monocytes	(%)	3 - 6	2 - 6
Granulocytes	(%)	49 - 74	53 - 79
RBC	($10^6/mm^3$)	4.37 - 5.63	3.90 - 5.10
HGB	(g/dl)	13.5 - 16.5	12.0 - 15.0
HCT	(%)	41 - 50	37 - 45
MCV	(μm^3)	83 - 101	84 - 96
MCH	(pg)	26 - 34	27 - 34
MCHC	(g/dl)	32 - 35	32 - 35
RDW	(%)	12 - 16	12 - 14
PLT	($10^3/mm^3$)	145 - 355	150 - 330
MPV	(μm^3)	7.3 - 9.0	8 - 10

PCT and PDW have not been established as indications for this product, in the United States. The use of PCT and PDW should be restricted to Research Use Only.

Expected values will vary with sample population and/or geographical location. It is highly recommended that each laboratory establish its own Normal ranges based upon the local population!

3.7. Accuracy

The Accuracy performance was proven by analyzing approximately 200 patient specimens on the ABX Micros 60 along with a commercially available Reference Analyzer, located in 3 different locations throughout the United States. The following table summarizes the data:

Tab.1-12:

Parameters		Site 1		Site 2		Site 3	
		n	R^2	n	R^2	n	R^2
WBC	($10^3/mm^3$)	198	0.992	209	0.997	203	0.995
RBC	($10^6/mm^3$)	198	0.995	212	0.995	204	0.990
HGB	(g/dl)	188	0.994	212	0.998	204	0.985
HCT	(%)	198	0.980	212	0.994	204	0.982
MCV	(μm^3)	198	0.988	212	0.987	204	0.980
MCH	(pg)	188	0.969	212	0.962	204	0.962
MCHC	(g/dl)	188	0.311	212	0.654	204	0.471
RDW	(%)	198	0.950	212	0.944	204	0.895
PLT	($10^3/mm^3$)	169	0.994	201	0.981	198	0.926
MPV	(μm^3)	191	0.639	204	0.709	203	0.863
Lymphocytes	(%)	98	0.975	110	0.991	119	0.461
Monocytes	(%)	98	0.552	104	0.787	119	0.461
Granulocytes	(%)	98	0.969	105	0.990	119	0.968
Reference Analyzers		Baker System 9000		Coulter S Plus IV		Coulter JT	

n: Number of specimens analyzed

R^2: Correlation coefficient from the regression curve Reference/ABX Micros 60

As mentioned above, this clinical study was performed at 3 different sites throughout the United States.

3.8. Leucocytes Differential count

Not available at the time of publication

3.9. Sample stability study

Not available at the time of publication

4. Limitations

Whilst every effort is taken by HORIBA Medical to investigate and indicate all known interference's, it is by no means possible to guarantee that all interference's have been identified. At all times, results should be validated and communicated only once all information relating to the patient has been assessed and taken into account.

4.1. Maintenance

In this Manual, specific Start-up, Shutdown, and Maintenance procedures are listed. The Maintenance procedures listed in this manual are mandatory for the proper use and operation of the ABX **Micros 60**.

Failure to execute any of these maintenance procedures may result in «Decreased Reliability» of the system. High emphasis on maintaining the system is strongly suggested.

4.2. Blood Specimens

All Blood samples should be collected using proper technique.

Consider all Specimens, Reagents, Calibrators, Controls, etc... that contain Human blood or serum as potentially infectious.
Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses or face shields, and follow other biosafety practices as specified in OSHA Bloodborne Pathogen Rule (29 CFR Part 1910, 1030) or other equivalent biosafety procedures.

4.2.1. Sample collection and mixing

When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric sample collection tubes.

(For USA Only). For additional information on collecting venous and capillary samples, refer to NCCLS document H3-A4 and NCCLS document H4-A4 (sept.1999).

The sample collection tube must be filled to the exact quantity of blood indicated on the tube itself. Any incorrectly measured blood sample collections will show a variation in results.

4.2.2. Sample Stability

Fresh Whole Blood specimens are recommended. The ICSH (*International Committee for Standardization in Hematology*) defines a Fresh blood specimen as «**One processed within 4 hours after collection**».

Well mixed Whole Blood specimens, collected in EDTA anti-coagulant and run within eight hours after collection, provide the most accurate results for all parameters. The white cell size distribution may shift when specimens are assayed between **5 and 20 Minutes** after collection and more than **8** hours after collection.

4.2.3. Anti-coagulants and their effects (on whole blood)

This is a list of commonly used anti-coagulants used for whole blood collections:

◆**Heparin:** Causes an increase in cell clumping, (WBC's and PLT's) and modifies cytoplasmic color with Romanowsky staining (Blue background). An increase in HCT and MCV with high heparin concentrations > 7.5UL /capillary tube.

◆**Trisodium Citrate:** Because the anti-coagulant is liquid, it includes a dilution estimated at 10/11 when filling 5ml tubes with whole blood. This anti-coagulant is used in coagulation. It is sometimes used in hematology when an EDTA - induced *Pseudothrombocytopenia* is suspected.

◆**Acid Citrate Dextrose (ACD) and Citrate Phosphate Dextrose with Adenine (CPDA):** The most commonly used anti-coagulants for cell concentrates (in particular Platelet concentrates) is normally not used for cell counting. There is no seriously known interference.

Anti-Coagulants used in blood collection may vary in the effects of changing the characteristics of the blood components. Caution is advised when selecting an anti-coagulant for analysis on the ABX Micros 60.

◆**EDTA:** Amoung the EDTA salts, EDTA K_2 (USA and Japan), EDTA K_3 (USA and Europe), and sometimes NA_2 EDTA are used. EDTA K_2 and EDTA K_3 are the most frequently used anti-coagulants for Hematology testing Worldwide. Mainly because they have been recommended by ICSH since 1993. The other EDTA salts are acceptable as well. EDTA can include *Pseudothrombocytopenia* (estimated frequency: 1/800) through Platelet clumping.

◆**Fluoride:** Was used before EDTA replaced it. No side affects as known so far.

4.3. Known Interfering Substances

Verification of any «Abnormal» test result, (*including Flagged results or results Outside their normal range*) should be performed using reference methods or other standard laboratory procedures for the conclusive verification of these abnormal results. The section below starts the list of the known limitations of automated blood cell counters which use the principle of impedance.

4.3.1. HCT (Hematocrit)

Red Blood cell Agglutination - May produce erroneous HCT and MCV values. Red blood cells agglutination may be detected by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear in such cases. Manual Laboratory methods may be required to obtain an accurate HCT value.

4.3.2. RBC Red Blood Cells (Erythrocytes)

The Red blood cell dilution contains all the formed elements in the blood: Erythrocytes, Leukocytes, and Platelets. During the counting of the RBC's, Platelets are below the RBC size minimum threshold, therefore they are not counted as RBC's.

Leukocytes - (White Blood cells) on the other hand, are included in the RBC count.However,since the normal ratio between Red blood cells and White blood cells is so extreme, the influence of counting the WBC's during the RBC count is negligible.

High WBC's - In rare cases where the WBC's are extremely high, the RBC count may be corrected, especially if the RBC count is extremely low in comparison to the high WBC count.

Agglutinated Red Blood cells - May cause a falsely low RBC count. Blood samples containing the agglutinated Red blood cells may be identified by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear.

Cold Agglutinins - IgM Immunoglobulins which are elevated in Cold Agglutinins disease, may lower RBC and PLT counts and increase the MCV.

4.3.3. WBC White Blood Cells (Leukocytes)

WBC results that exceed the linearity limits of the system will require a Dilution of the blood sample. Re-assaying the diluted blood sample will help to obtain the correct assay value. As in some Leukemia patients.

NRBC - Immature (*Nucleated Red Blood Cells*) will be counted in the WBC (*White Blood Cell*) parameter. If the number of Nucleated Red Blood cells is sufficient enough to activate an «L1 Alarm», such interference will be detected. However, a Manual differential white blood cell count, performed on a stained blood smear, will confirm the presence of NRBC's.

When NRBC's are present in the WBC count, the formula for correcting the WBC parameter is as followed:

Corrected WBC = (Counted WBC's x 100) / [100 + (# of NRBC's/100 WBC)]

Non-lysed Red Cells - In particularly rare instances, the erythrocytes in the blood sample may not completely lyse when lysing reagent is added in the WBC Chamber. These non-lysed Red blood cells may be detected on the WBC Histogram with an «L1 Alarm» or as an elevated baseline on the (*Left leading edge*) of the Lymphocytes population in the WBC Histogram. Non-lysed erythrocytes will also cause a falsely elevated WBC count.

Following the Manual differential white blood cell count, the WBC assay value «Must be corrected to subtract the NRBC's from the total white blood cell count. This will give a true and correct count of the actual WBC's.

Multiple Myeloma - The precipitation of proteins in Multiple Myeloma patients may give elevated WBC counts.

Hemolysis - Hemolyzed specimens contain Red cell Stroma which may elevate WBC counts.

Leukemia - A very low WBC count may result in this disease state because of possible increased fragility of the leukocytes leading to some destruction of these cells during counting. These white cell fragments will also interfere with the white cell partial differential parameters: LYM % and #, MON % and #, GRA % and #. A suspiciously low WBC count may also be seen in patients with Lymphocytic Leukemias due to the presence of abnormally «Small» lymphocytes which may not be counted by the instrument.

Chemotherapy - Cytotoxins and Immunosuppressive drugs may increase the fragility of the leukocytes which may cause low WBC counts.

Cryoglobulins - Increased levels of Cryoglobulins that may be associated with Myeloma, Carcinoma, Leukemia, Macroglobulineima, Lymphoproliferative disorders, Mestastic turmors, Auto-immune disorders, Infections, Idiopathic disease, Aneurism, Pregnancy, Thromboembolic phenomena, Diabetes, ...etc, which can elevate the WBC, RBC, and PLT counts along with the HGB value. The specimen can be warmed up to 37^0C and re-analyzed immediately. If warming the specimen has no effect on the count, a Manual WBC, RBC,and or PLT count can be performed.

Increased Turbidity - may also be seen in cases where the red blood cells are resistant to the lysing action. This condition will cause a falsely elevated Hemoglobin result, but may be detected by observing the abnormal MCH and MCHC values, also the increased baseline on the *(Left leading edge*) of the WBC histogram. Erroneous Hemoglobin results will also cause the results of the MCH and MCHC to be erroneous as well.

4.3.4. HGB (Hemoglobin)

Turbidity of the Blood sample - Any number of physiologic and/or theraputic factors may produce falsely elevated Hemoglobin results. To obtain accurate HGB results when increased turbidity of the blood sample occurs, determine the cause of the turbidity and follow the appropriate Method below:

1- **Elevated WBC:** An extremely elevated WBC will cause excessive light scatter from the L.E.D. In these cases, use Reference (Manual) methods. The Diluted sample should be Centrifuged, and the Supernatant fluid measured with a Spectrophotometer.

2- **Elevated Lipids:** Elevated Lipids in the blood will give the plasma a «milky» appearance. This condition can occur with Hyperlipidemia, Hyperproteinemia(*as in gammapathies*), and Hyperbilirubinemia. Accurate Hemoglobin measurement can be achieved by using reference (Manual) methods and a plasma blank

Increase in Turbidity may also be seen in cases where the Red blood cells are resistant to the Lysing action. This condition will cause a falsely elevated HGB result, but may be detected by observing the abnormal MCH and MCHC values, and the increased baseline on the *(Left leading edge*) of the WBC Histogram. Erroneous HGB results will cause the results of the MCH and MCHC to be erroneous as well.

Fetal Bloods - The mixing of fetal and maternal bloods may produce a Falsely elevated Hemoglobin value.

4.3.5. MCV (Mean Corpuscular Volume)

Red Blood cell Agglutination - May produce an erroneous MCV value. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear. In such cases, Manual methods may be required to obtain an accurate MCV value.

Excessive Numbers of Large Platelets - and /or the presence of an excessively High WBC count may interfere with the accurate determination of the MCV value. Careful examination of a stained blood smear may reveal the error.

4.3.6. MCH (Mean Corpuscular Hemoglobin)

The MCH is determined, according to the HGB value and the RBC count. The Limitations listed for HGB and RBC will have an effect on the MCH and may cause erroneous values.

4.3.7. MCHC (Mean Corpuscular Hemoglobin Concentration)

The MCHC is determined, according to the HGB and HCT values. The Limitations listed for HGB and HCT will have an effect on the MCHC and may cause erroneous values.

4.3.8. RDW (Red cell Distribution Width)

The Red blood cell distribution width is determined, according to the RBC count. The red blood cells pass through a Micro-aperture that will generate electronic pulses, as the cells pass through it. These pulses are then Grouped according to size, Thresholded, and calculated to form a Histogram (Distribution curve). This distribution curve is then used to calculate the distribution of the Red blood cells as a percentage of the curve. This curve is then used in determining the RBC size abnormalities as in Anisocytosis.

Agglutinated Red Blood cells - May cause a falsely low RBC count and erroneous RDW's. Blood samples containing the agglutinated RBC's may be detected by observing abnormal MCH and MCHC values, as well as examination of a stained blood smear.

Nutritional Deficiency or Blood Transfusion - May cause elevated RDW results due to Iron, Vitamin B12, or Folate conditions. High RDW's may also be present from Bi-modal RBC distribution from Transfused Blood. This will be detected by the RBC Histogram showing 2 distinctive peaks on the distribution curve.

4.3.9. PLT (Platelets)

Very Small Erythrocytes - Microcytes, Erythrocyte's fragments - Schistocytes, and WBC fragments may interfere with the proper counting of Platelets, and cause elevated Platelet counts.

Agglutinated Red Blood cells - May trap platelets, causing an erroneously Low platelet count. The presence of agglutinated RBC's may be detected by observing abnormal MCH and MCHC values, and by careful exmination of a stained blood smear.

Giant Platelets in Excessive Numbers - May cause an erroneously low platelet count since these Large platelets may exceed the Upper Threshold limit for platelets, and are not counted as platelets.

Chemotherapy - Cytotoxic and Immunosuppressive drugs may increase the fragility of these cells which may cause Low platelet counts. Reference (Manual) methods may be necessary to obtain an accurate platelet count.

Hemolysis - Hemolyzed specimens contain Red blood cell Stroma which may cause elevated platelet counts.

A.C.D. Blood - Blood anti-coagulated with Acid-Citrate-Dextrose may contain Platelet Aggregates which could give falsely low platelet counts.

RBC Inclusions - Erythrocyte inclusions such as Howell-Jolly bodies, Heinz bodies, Siderotic and Basophilic granules,.....etc, may produce considerably elevated platelet counts.

Platelet Agglutination - *Clumped Platelets* due to poor collection techniques or platelet satellitosis caused by EDTA activation of Immunoglobulins may cause a Low platelet count and/or an elevated WBC count.

These types of specimens should be re-collected in Sodium-citrate anticoagulant and re-analyzed «For Platelets Only»!

4.3.10. MPV (Mean Platelet Volume)

Giant Platelets - that exceed the upper thresholding of the platelet channels, may not be counted as platelets. consequently, these larger platelets will not be included in the instrument's calculations of the mean platelet volume.

Blood Samples collected in EDTA will not maintain a stable Mean Platelet Volume. Platelets collected in EDTA will swell with time and temperature

Agglutinated Red Blood cells - May trap Platelets, causing an erroneous MPV result. The presence of Aggultinated erythrocytes may be detected by observing abnormal MCH and MCHC values, and by careful examination of a stained blood smear.

Very Small Erythrocytes - Microcytes, Erythrocyte fragments - Schistocytes, and White Blood cell fragments may interfere with the proper sizing and counting of the Platelets.

Chemotherapy - May also affect the Sizing of Platelets.

4.3.11. LYM # (Lymphocyte count Absolute Number)

The Lymphocyte count is derived from the WBC count. The presence of Nucleated Red Blood cells (NRBC), certain Parasites, and erythrocytes that are resistant to the Lysing action, may interfer with an accurate LYM # count. Limitations listed for the WBC count pertain to the LYM # count as well.

4.3.12. LYM % (Lymphocyte Percentage)

The Lymphocyte percentage is determined, according to the WBC count and the number of Lymphocytes. The presence of NRBC's, certain parasites, and erythrocytes that are resistant to the Lysing action, may interfere with an accurate LYM % count. Limitations listed for the WBC count pertain to the LYM % count as well.

4.3.13. MON # (Monocyte count Absolute Number)

The Mononuclear cell count is derived from the WBC count. The percentage of Large Lymphocytes, Atypical Lymphocytes, Lymphoblasts, and an excessive number of Basophils may interfer with an accurate Monocyte count.

4.3.14. MON % (Monocyte Percentage)

The Monocyte percentage is determined, according to the WBC count and the number of Monocytes. The presence of Large Lymphocytes, Atypical Lymphocytes, Lymphoblasts, and an excessive number of Basophils may interfere with an accurate Monocyte % count.

4.3.15. GRA # (Granulocyte count Absolute Number)

The Granulocyte cell count is derived from the WBC count. The excessive presence of Eosinophils, Metamyelocytes, Myelocytes, Promyelocytes, Myeloblasts, and Plasma cells may interfere with an accurate Granulocyte # count.

4.3.16. GRA % (Granulocyte Percentage)

The Granulocyte percentage is determined, according to the WBC count and the number of Granulocytes. The excessive presence of Eosinophils, Metamyelocytes, Myelocytes, Promyelocytes, Myeloblasts, and Plasma cells may interfere with an accurate Granulocyte % count.

5. Reagent Specifications

Do not use the instrument operational caps when reagents are left off the instrument.

HORIBA Medical Manufactures and Markets Reagents, Calibrators, and Quality Control bloods specially designed for use with the ABX Micros 60 analyzers. The use of products not recommended by HORIBA Medical may give erroneous results or instrument operation problems. Contact your local HORIBA Medical center for all information regarding the recommended products.

The **HORIBA Medical** reagents specified for this instrument have been approved in accordance with the European Directive 98/79/CE (Annex III) for in-vitro medical devices.

Refer to **Reagent Leaflets** for all reagent specifications.

The CD ROM RAX055 delivered with your instrument provides reagents, controls and calibrators leaflets/msds. Latest versions of these documents are available on www.horiba.com

- Allow your reagents to return to room temperature before use, to avoid gas bubble emissions.
- Never pour the remaining quantity of a reagent previously being used into the new reagent replacing it. This will eliminate any cross contamination to the new Reagent.
- Never leave a reagent container open during use. Use the appropriate caps provided with the instrument. Order new reagent caps if lost or misplaced.
- Check with your shipping company and verify that your reagent shipment has not encountered important temperature differences during transportation.
- Clean any reagent spillage with water as soon as possible in order to prevent Crystallization of the reagent and Oxidation of the metal parts of the instrument.
- Never pour reagents into the laboratory waste water drainage system. Follow Local/National regulations for chemical waste disposal. Apply neutralization procedures when necessary.
- It is necessary to flush the reagent lines with distilled water, then dry them when the instrument is going to be shipped to any location or will be left without operating for an extended period of time. Contact your Local **HORIBA Medical** *SERVICE CENTER* for more information about this procedure.
- These reagents are used for Invitro, *out side the body*, diagnostics.

6. Reagent Consumption

Make sure a Startup and a Control Blood have been performed after a reagent replacement.

Reagent consumption is given in milliliters (ml). It has been calculated from an average on 100 cycles for a specific program version.

Program version: V1.7.0

Tab.1-13: Reagent Consumption

Cycle	Diluent	Lyse	Cleaner	Minoclair
Startup	23.2	0.5	///	///
Standby	///	///	13.9	///
Analysis	15.8	0.5	0.9	///
Prime All Reagents	42.0	42.0	42.0	///
Prime Diluent	26.2	///	///	///
Prime Lyse	///	10.4	///	///
Prime Cleaner	///	///	5.4	///
Auto Clean	15.9	0.5	13.8	///
Concentrated Cleaning	16.0	0.5	1.9	6.0
Cal Photometer	16.2	0.5	///	///
Backflush	///	///	///	///

7. Waste Handling Procedure

If required, waste can be neutralized before being discarded. Follow your laboratory's protocol when neutralizing and disposing of waste.

Dispose of the waste container according to the local or national regulatory requirements

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc...). Follow your local and/or national guidelines for biohazard waste disposal.

Contents

1. Description 2-2
1.1. Overview 2-2
1.2. Front view (covers opened) 2-2
1.3. Left side view (covers opened) 2-3
2. Technology 2-3
2.1. Sampling 2-3
2.2. Dilutions 2-4
2.2.1. WBC/HGB 2-4
2.2.2. RBC/PLT 2-4
2.3. CBC Measurement Principles 2-5
2.3.1. RBC/PLT 2-5
2.3.2. HGB 2-7
2.3.3. HCT 2-8
2.3.4. MCV, MCH & MCHC 2-8
2.3.5. RDW 2-8
2.3.6. MPV 2-8
2.3.7. PCT 2-8
2.3.8. PDW 2-9
2.3.9. WBC 2-9

1. Description

1.1. Overview

1- LCD screen display

2- Key pad control panel

3- Smart card reader (optional)

4- Reagent compartment

5- Sample probe and analysis Start bar

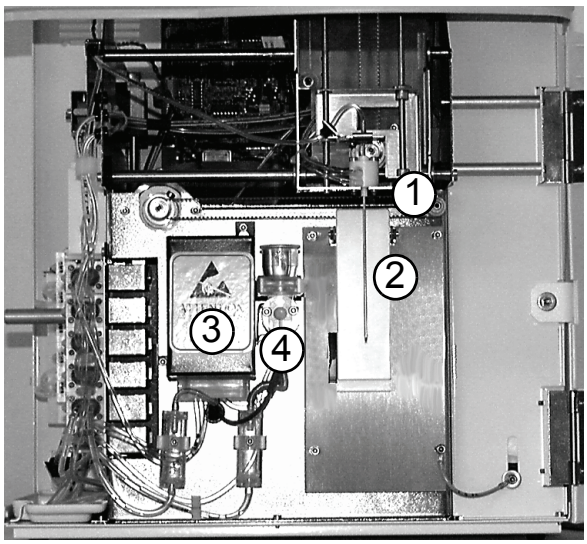
1.2. Front view (covers opened)

1- Carriage Assembly

2- Sample probe and Analysis Start bar

3- WBC/HGB Chamber

4- RBC Chamber



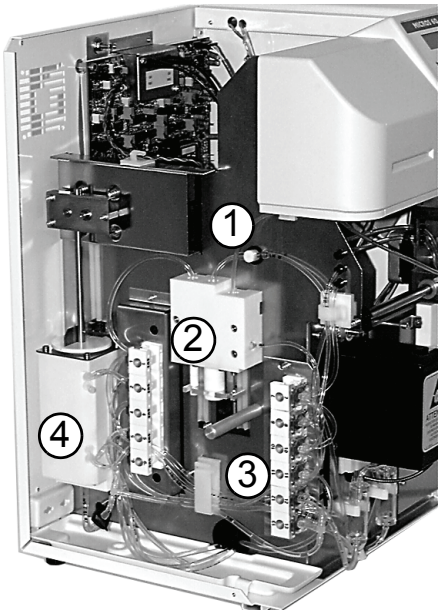
1.3. Left side view (covers opened)

1- Diluent Temperature Sensor

2- Liquid Syringe

3- Valve Block

4- Vacuum/Waste Chamber



2. Technology

2.1. Sampling

1- Blood Collection tube cap is removed

2- The Tube is placed beneath the sample probe.

3- The Tube is move upwards and the sample probe enters into the blood.

4- The Manual sample bar is pressed and aspiration of 10µl of Blood occurs.

5- Needle Carriage assembly moves to the Left, over the WBC/HGB Chamber.

6- The External Sample probe rinses.

7- Blood sample is delivered into the WBC Chamber for the First dilution.

8- Aspiration of 28.3µl of diluted blood from the WBC Chamber.

9- Needle Carriage assembly moves to the Right, over the RBC/PLT Chamber.

10- The External Sample probe rinses.

11- Diluted Blood sample is delivered into the RBC Chamber for the RBC/PLT measurement

2.2. Dilutions

2.2.1. WBC/HGB

Tab.2-1: WBC/HGB Dilution

WBC/HGB Dilution	
Initial blood volume	10.0µl
Volume of ABX Minidil LMG	2100µl
Volume of ABX lyse	500µl
Final dilution ratio	1/260

Tab.2-2: WBC Measurement

WBC Measurement	
Method	Impedance
Aperture diameter	80 µm
Count Vacuum	-200mb
Count period	2 x 5 seconds
Temperature reaction	ambient

Tab.2-3: HGB measurement

HGB measurement	
Wavelength	550nm
Count period	2 x 5 seconds
Temperature reaction	ambient

10µl of blood sample contained in the sample probe is pushed with 1.2ml of ABX Minidil LMG along with 0.5ml of ABX Minidil LMG from the outer probe into the WBC/HGB Chamber.

0.4ml of ABX Minidil LMG is added the WBC/HGB Chamber making the diluent volume 2.1ml.

0.5ml of ABX lyse is added to the mixture.

This makes the total dilution for WBC/HGB.

2.2.2. RBC/PLT

Tab.2-4: RBC/PLT dilution

RBC/PLT dilution	
Initial Diluted blood volume	30µl (1/170)
Volume of ABX Diluent	2500µl
Final dilution ratio	1/15000

Tab.2-5: RBC/PLT measurement

RBC/PLT measurement	
Aperture diameter	50µl

Tab.2-5: RBC/PLT measurement

RBC/PLT measurement	
Count Vacuum	-200mb
Count period	2 x 5 seconds
Temperature reaction	ambient

28.3µl of diluted blood is aspirated from the WBC chamber. The needle carriage assembly moves to the right over the RBC/PLT chamber.

2.0ml of Diluent and the 28.3µl of diluted blood is injected into the RBC/PLT chamber from the inner sample probe.

0.5ml of Diluent is added to the dilution in the chamber from the outer sample probe. This makes the total dilution for the RBC/PLT.

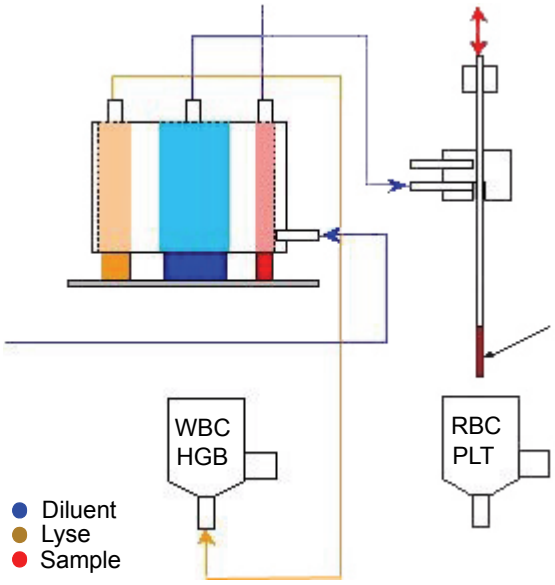


Fig.2-1: sample dilution

2.3. CBC Measurement Principles

2.3.1. RBC/PLT

The RBC's and PLT's are measured by an electronic impedance variation principle. This means that an electronic field is generated around the micro-aperature in which the blood cells pass through. The cells create a resistance in the electronic field as they pass through the Calibrated micro-aperture. This inturn causes an electronic pulse to be generated which is amplified, measured, and then mathematically calculated to create a numerical value.

First the 28.3µl Diluted Blood sample is diluted in an Electrolytic Diluent (electronic current conducting fluid) mixed, then pulled through a calibrated micro-aperture. There are two electrodes that are placed on each side of the aperture and a constant electronic current passes between them.

As the blood cells pass through the aperture, they create resistance (Impedence) in the electronic field between the two electrodes. Since the current is constant and remains unchanged, the larger the cell is, the «more» resistance it has. The smaller the cell is, the «less» resistance it has. The voltage which measures the cells is proportional to the cell size. The larger the cell, the higher the voltage will be. The smaller the cell, the lower the voltage will be.

These electronic voltages vary in pulse size as cells pass through the aperture. The pulses are then channeled according to pulse size. The pulses are then thresholded, grouped, then mathematically calculated to create a numerical value for the determination of RBC's and PLT's.

2.3.1.1. Results

A certain amount of cells will pass through the Calibrated Micro-aperture within a specific time frame. They are then measured by pulse height, Thresholded, grouped by size, and Mathematically calculated along with the Calibration Coefficient to give a final numerical value for both RBC's and PLT's.

2.3.1.2. RBC and PLT Histograms

The RBC and PLT Histograms are determined by thresholding of the electronical pulses. These pulses are then grouped according to size by channeling the pulses into the correct size category. The electronic pulses are smoothed mathematically, and plotted on a graph.

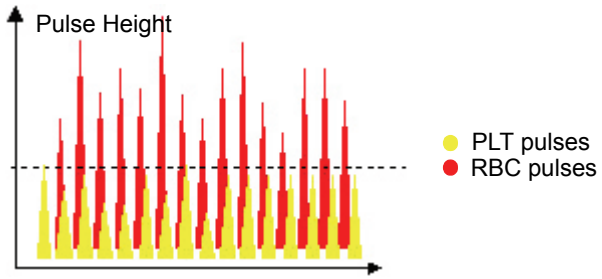


Fig.2-2: Cells passsing through the aperture creating electronic pulses

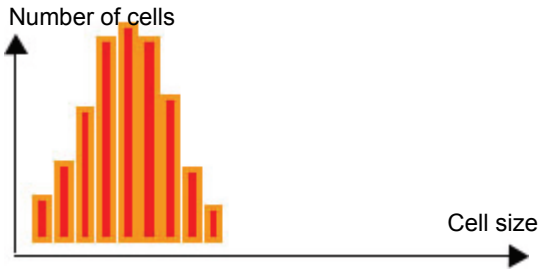


Fig.2-3: RBC Pulses grouped according to the number and the size of the cells

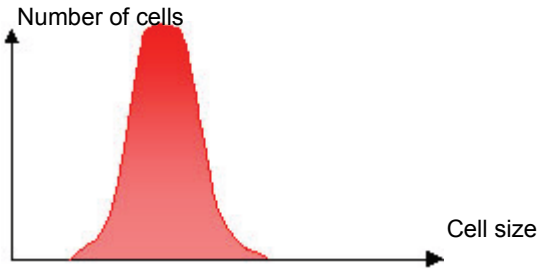


Fig.2-4: RBC Pulses electronically calculated and smoothed: RBC Distribution curve

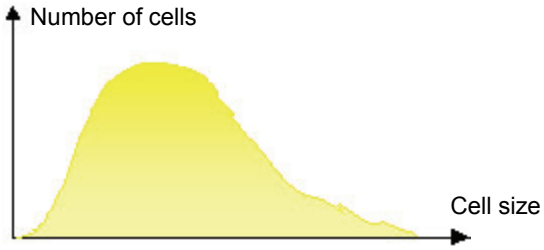


Fig.2-5: PLT pulses electronically calculated and smoothed: PLT distribution curve

RBC Histogram: is an electronic Distribution and mathematical calculation of the RBC's placed into 256 Channels of volumetric sizing from 30fl to 300fl.

PLT Histogram: is an electronic distribution and mathematical calculation of the PLT's placed into 128 channels of volumetric sizing from 2fl to a mobile threshold between the high end platelets to the Low end Red Blood Cell Thresholds.

(fl = femtoliters) A microscopic volumetric unit of measurement. This is a 3-dimentional measurement used to determine the volume of Microscopic particles.

2.3.2. HGB

The Hemoglobin measurement is based on a Startup cycle. This cycle includes a Hemoglobin Blank test sequence which includes 2 Hemoglobin blank measurements. Each analysis cycle run after Start-up also has a Hgb Blank measurement which is compared to the initial Start-up Hgb Blank. Each analysis cycle run thereafter compares the Hgb Blank reading to the previous cycle Hgb Blank reading.

During the WBC analysis cycle, 0.5ml of Lyse Reagent is added to 2.05ml of diluted blood in the WBC Chamber. The Lyse reagent contains potassium ferricyanide [Fe(Cn)]K, and potassium cyanide [KCN]. This lysing reagent breaks down the RBC Cell membrane and releases the Hemoglobin within the RBC.

The Hemoglobin then combines with the potassium cyanide to form a chromogenous cyanmethemoglobin compound. This chemical compound is measured by Spectrophotometry, through the optical pathway in the WBC chamber. The light wavelength of measurement is at 550nm.

Results, The Hgb results are given as such:

HGB = Log(blank value/Sample value) x the Calibration Coefficient.

2.3.3. HCT

The Hematocrit is a combination measurement of electronic pulses and mathematical calculations. All the RBC pulses are grouped into various sizes. Each group pulse height is then averaged. all the pulse height averages are then averaged one final time for a mean average of all the RBC pulse heights. This is a function of the numeric integration of the MCV. Results are given as a percentage of this integration.

2.3.4. MCV, MCH & MCHC

- MCV (Mean Cell Volume), is calculated directly from the entire RBC histogram.
- MCH (Mean Cell Hemoglobin), is calculated from the Hemoglobin value and the RBC count. Calculations are as followed:

$$MCH\ (pg) = HGB/RBC \times 10$$

(pg): Picograms

- MCHC (Mean Corpuscular Hemoglobin Concentration), is calculated according to the Hemoglobin and Hematocrit values. Calculations are as followed:

$$MCHC\ (g/dl) = HGB/HCT \times 100$$

2.3.5. RDW

The RDW (Red cell Distribution Width) is used to determine erythrocyte abnormalities linked to Anisocytosis. The RDW will enable you to follow the evolution of the width of the RBC Histogram in relation to the number of cells and their average volume. This is also a calculation of the RBC Histogram.

Calculations are as followed:

$$RDW\ (\%) = K\ SD/MCV$$

K : .....Calibration Coefficient for RDW.
SD : .....Standard Deviation according to statistical studies on cell distribution.
MCV : .....(Mean Cell Volume) of the erythrocytes.

2.3.6. MPV

The MPV (Mean Platelet Volume), is directly calculated from the Platelet histogram distribution curve. This calculation is almost the same as the MCV.

2.3.7. PCT

Thrombocrit (Plateletcrit), is calculated according to the formula:

$$PCT\ \% = PLT\ (10^3/mm^3) \times MPV\ (\mu m^3) / 10\ 000$$

2.3.8. PDW

The PDW (Platelet Distribution Width) is calculated from the Platelet Histogram/ Distribution curve.

The PDW is represented by the width of the curve between 15% of the number of platelets starting from the Low Threshold 2fl (S1) and 15% of the number of platelets begining with the Variable High Threshold (S2). The PDW determination area is shown by the distribution curve below.

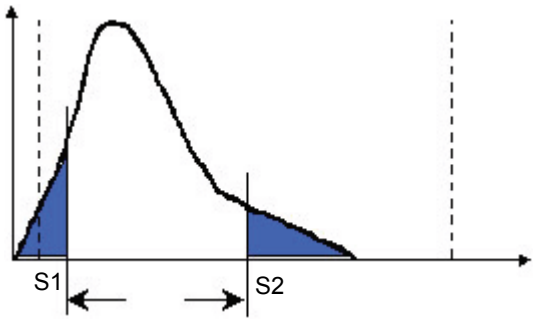


Fig.2-6: Platelet distribution curve

PCT and PDW are not available in the United States. These parameters are strictly used for research and investigational purposes «Only».

2.3.9. WBC

The WBC Measurement principles are based upon the same as the RBC/PLT measuring principles. The WBC count is performed in the WBC/HGB Chamber. The electronic signal processing device places and electronic threshold between the WBC's and the PLT's. The electronic pulses are then placed into 256 Channels according to pulse size. The pulses are then Thresholded, grouped, then mathematically calculated to create a numerical value for the determination of WBC's.

2.3.9.1. WBC Histogram

The WBC Histogram is a distribution study that reveals the following 3 types of White blood cell sub-populations: (Lymphocytes, Monocytes, and Granulocytes). The Diluent and Lyse of the ABX **Micros 60** play a very important part when sizing the WBC subpopulations in the WBC distribution curve.

2.3.9.2. Differential Measuring principles

- **Diluent and Lysing action**:

The Diluent preserves and prepares the WBC cell membrane for the differential reaction. The Lysing reagent has a differential mode of action on the WBC cytoplasmic membranes.

When the Lyse reacts with the Lymphocyte cytoplasmic membrane, it allows the release of water soluble cytoplasm and shrinks the membrane around the nucleous.

When the Lyse reagent reacts with the Monocyte cytoplasmic membrane, it has an intermediate reaction which keeps the cell somewhat stable, maintaining its large size in comparison to the lymphocytes.

When the Lyse reagent reacts with the Granulocytes, it has a limited reaction due to a molecule in their cytoplasmic structure which protects them from shrinking action of the lyse. This inturn makes the Granulocytes the larger of the WBC sub-populations in the cell differentiation.

After the Differential lysing action, the ABX Micros 60 analyses the height of each electronic pulse as the WBC's pass through the Micro-aperture. The pulses are then Channeled, Thresholded, grouped according to their size from 30fl to 450fl, and calculated mathematically to create the WBC distribution curve which inturn is known as the WBC Histogram.

The 3 sub-populations of WBC's are placed accordingly as to the number of cells and size of the cells in each group.

The distribution of the WBC sub-populations are as followed:

- The Lymphocytes are between 30 - 100fl.
- The Monocytes are between 100 - 150fl.
- The Granulocytes are between 150 - 450fl.

This inturn creates the term (LMG's) for a 3 part WBC differential on the ABX Micros 60.

The Granulocytes subpopulation of the WBC's contains 3 sub-populations within itself, which are somewhat the same in nature.
They all contain Cytoplasmic granuler material which stain various colors when viewed microscopically. These 3 sub-populations are as followed:
- **Neutrophils**
- **Eosinophils**
- **Basophils**

The distribution of these cells depends on the pathological and physiological conditions of the individuals analyzed

Pathological cells will, of course, place themselves in different zones within the WBC distribution curve. Mobile and Fixed Alarm flags will alert the lab operator of the presence of these Pathological elements.

- **Results**

The Lymphocytes, Monocytes, and Granulocytes results are given as a percentage of the entire WBC count, along with absolute numbers, as well, to reflect on the actual WBC count itself. They are presented as followed:

LYM%	LYM #
MON%	MON#
GRA%	GRA#

Contents

1. Startup checks 3-2
1.1. Reagent level checks 3-2
1.1.1. Bottled units 3-2
1.1.2. Minipack Units 3-2
1.2. Printer Power and On-line Checks 3-3
1.3. Instrument Startup 3-3
1.4. Blood Sample Collection 3-4
2. Daily Quality Control & Calibration verification 3-5
3. Sample selection and identification 3-6
3.1. Sample identification modes 3-6
3.1.1. US Mode 3-6
3.1.2. Standard Mode 3-6
4. Running Samples 3-8
4.1. Preliminaries 3-8
4.2. US mode 3-8
4.3. Standard mode 3-8
4.4. Automatic Cleaning Cycle 3-8
4.5. End of the day rinsing 3-9
5. Results 3-10
5.1. ABX **Micros** 60 OS/OT8 3-10
5.1.1. Displayed Results 3-10
5.1.2. Identification 3-10
5.1.3. Flags 3-10
5.1.4. Results Printout 3-11
5.2. ABX **Micros** 60 OS/OT16 3-13
5.2.1. Displayed Results 3-13
5.2.2. Identification 3-13
5.2.3. Flags 3-13
5.2.4. Result printout (US mode example) 3-14
5.3. ABX **Micros** 60 OS/OT18 3-15
6. Flags 3-15
6.1. Normal Limits 3-15
6.2. Flags causing analysis reject 3-15
6.2.1. Results Exceeding Linear range 3-15
6.2.2. Results Rejected 3-16
6.2.3. Results Comparable 3-16
6.2.4. HGB Blank Reference 3-16
6.3. Morphology Flags 3-17
6.3.1. Flags on PLT Distribution curve 3-17
6.3.2. Flags on WBC Distribution curve 3-17

1. Startup checks

At the beginning of each day, before running a Startup, check if the waste container needs to be emptied.
During the operation, do not remove the reagent tubes and the waste liquid tube under any condition.

1.1. Reagent level checks

Make sure a Startup and a Control Blood have been performed after a reagent replacement.

1.1.1. Bottled units

Individual reagents: first thing prior to Startup is checking the levels of each reagent before operating the system. If a reagent level is «Low», replace the reagent and prime the new reagent using the following steps through the instrument menus.

Never pour reagent from one container into another! Any type of contamination present in the old reagent will affect the new reagent. Unacceptable background counts will most likely occur especially for PLT's. Always use the reagents caps provided with the instrument to prevent Reagent pollution or oxidation.

Menu access
Main Menu / 4 - Service / 3 - Prime
then select the reagent or reagents that need to be primed.
1- All Reagents
2- Diluent
3- Lyse
4- Cleaner

1.1.2. Minipack Units

All Reagents and a Waste bladder are contained in one Minipack: When a Reagent Pack runs low, the instrument will display a message stating that the reagent pack is low. This warning message is given according to the numbers of CBC cycles left in the pack.

To replace the Pack, follow the steps through the menus:

Menu access
Main Menu
4- Service
3- Prime
3- Prime
2- Pack unit
1- Change Pack

The ABX Micros 60 will show the remaining steps to follow on the LCD display. Once this Pack replacement is complete, the instrument automatically resets the CBC cycle counter to 160 cycles.

1.2. Printer Power and On-line Checks

Prior to instrument startup, always check the printer to verify that the power is turned «ON» and that the LED's are in the ready state. Check that the printer has sufficient paper for the daily operations. Check the alignment of the paper if your printer is a tractor feed printer.

1.3. Instrument Startup

Power «ON» the instrument by pressing the ON/ OFF switch, located on the back, lower center of the rear panel. The LCD display will show the following:

Screen display
Please wait for 3 Min

This indicates an instrument warm-up period for the internal electronics.

Once the instrument warm-up phase is complete, the front panel L.E.D. will turn from «Red» to «Green» indicating that the initialization phase is complete. The ABX **Micros 60** will now automatically run a STARTUP cycle, if and only if the instrument has been programmed for an Auto-Startup cycle (see Section 5, 4.3. Choosing Startup Cycle, page 5-11)

If the ABX **Micros 60** does not automatically run a Startup cycle after the initialization phase is complete, press the «Startup» key on the instrument front panel to initiate the cycle.

The ABX **Micros 60** will perform a Startup cycle which primes all the reagents, checks the electronics, and mechanical movements. Then the instrument will perform a blank cycle for a Background count (an analysis cycle based on reagents without any blood sample). The instrument then prints out the blank cycle results.

Background Limits

Check and verify that the Background counts do not exceed the following parameter limits:

WBC 0.3 10^3/ mm^3
RBC 0.02 10^6/ mm^3
HGB 0.3 g/dl
PLT 10 10^3/ mm^3

If the Background count is above any of the parameter limits, the ABX **Micros 60** will automatically perform another STARTUP cycle.

If the Problem persists after 3 consecutive cycles, a message will be printed out stating «Startup Failed»

Refer to the «Maintenance and Troubleshooting» (See Section 6, 2. Troubleshooting, page 6-17) for identifying and resolving the problem in question.

If the HGB blank test is unacceptable during the first Startup cycle, 2 more startup cycles will be performed. If all 3 startup cycles fail the HGB blanck test, an error message will be printed out stating «startup failed, HGB reference failed»

If any analysis cycles are run prior to a Startup cycle, a message will be displayed on the LCD and printed out stating: «Startup cycle not initiated»

When the ABX **Micros 60** has not been used within 4 hours of the last cycle, it is necessary to perform a STARTUP cycle before running an analysis cycle.

1.4. Blood Sample Collection

Refer to Section 1, 4.2. Blood Specimens, page 1-13. for collection requirements. Blood samples must be gently and thoroughly mixed with a rocking or tilting motion just before placing the sample into the tube holder for the analysis cycle.

2. Daily Quality Control & Calibration verification

Before analyzing any patient blood samples, it is recommended that the Operator performs Quality Control analysis on 3 levels of Control Blood Material, (Low, Normal, and High), to verify that the ABX **Micros 60** is performing within the specified ranges of the Quality control material.

Please refer to Section 4, 1. Quality Control , page 4-2 in order to perform the Control sample run.

General recommendations on calibration
The calibration on HORIBA Medical instruments is an exceptional procedure, which must be carried out particularly in case of certain technical interventions (installation, maintenance, service intervention). The calibration should not be carried out to compensate a drift on a result due for example to a clogging of the instrument.

Running control blood

Mix the sample gently and thoroughly.
Remove the cap from the sample tube.
Place the sample beneath the sample probe.
Raise up the tube so that the sample probe lowers into the blood, and press the manual sample bar or press the «Startup» key.
The analysis cycle will begin.

If any results are out of their acceptable ranges, perform the following steps:

1- Rerun the Control blood.

2- Clean the system, see Section 6, 1.3.6. Concentrated Cleaning, page 6-11. Re-run the sample.

3- Open a new vial of control material.

4- Call your local **HORIBA Medical** Technical support representative before re-Calibrating the system.

3. Sample selection and identification

3.1. Sample identification modes

3.1.1. US Mode

The Sample Identification modes are selected from the Setup menu in the system configuration (see Section 5, 4.7. Choosing sample identification mode , page 5-14 for selecting the Mode for your daily operations).

This mode requires a patient identification on each analysis run, this mode also allows the use of a barcode reader if applicable.

3.1.1.1. US mode «Without» barcode reader

Entering Identification

Press the «ID» key on the front panel to enter the sample ID (13 alphanumeric Numbers and/or Letters characters are available)
Letters can be entered by using the front panel «Up» and «Down» arrow keys.
Press the «Enter» key after each Alpha character entry.
The Number keys can be used up to 13 consecutive characters if No alpha characters are used before, pressing the «Enter» key.
The sample Identification will be held in Memory until the cycle is complete.

3.1.1.2. US mode «With» barcode reader

Entering Identification

Press the «ID» key.
Place the sample in front of the reader so that the Label can be identified. When the reading is complete, a «Beep» tone is heard and the label identification will be displayed on the LCD screen.
Press the «Enter» key to save the current identification.
Or press the «Esc» key to display the previous identification.

The barcode reader is a special setup function in the system configuration. Before using this setup, the Barcode Reader must be configured on the main circuit board of the ABX Micros 60. If you require a barcode reader for sample identification, please contact your local HORIBA Medical Service Representative for installation and setup of this device.

3.1.2. Standard Mode

If the Standard Mode identification has been selected from the setup menu (see Section 3, 3.1. Sample identification modes, page 3-6), proceed as follows:

Entering Identification

Press the «ID» key to enter the sample «Run #»
Use the Number keys only. Enter a run number from 1 to 99999.
Press the «Enter» key to save the current Run #
Or press the «Esc» key to display the previous Run #.

Once the Identification has been entered, a message will appear on the LCD display stating «Press the sampling bar», press the manual sampling bar or press the «Startup» key on the front panel of the ABX **Micros 60** to start the analysis cycle.

4. Running Samples

4.1. Preliminaries

1- Run the Quality Control blood, all 3 levels and verify that the results are within their specified limits (see Section 4, 1. Quality Control , page 4-2).

2- Mix the blood sample gently and thoroughly.

4.2. US mode

Running analysis

Press the «ID» key and enter the patient Identification (See "3.1.1. US Mode , page 6").
Remove the cap from the sample tube.
Place the sample beneath the sample probe, raise the sample tube upwards so that the sample probe enters into the blood.
Press the manual sample bar and analysis will begin. Press the «Startup» key on the front panel if the system does not respond to the Manual sample bar.

4.3. Standard mode

Running analysis

Press the «ID» key and enter the Run # (See "3.1.2. Standard Mode , page 6").
Remove the cap from the sample tube.
Place the sample beneath the sample probe, raise the sample tube upwards so that the sample probe enters into the blood.
Press the manual sample bar and analysis will begin. Press the «Startup» key on the front panel if the system does not respond to the Manual sample bar.

If the instrument has not been in operation for 1/2 hour and an analysis cycle is initiated, the ABX Micros 60 will start a HGB Reference cycle. The message «Please wait» will be displayed on the LCD screen. Once the HGB reference cycle is complete, the message «Press the sampling bar» will appear.

4.4. Automatic Cleaning Cycle

The ABX Micros 60 will perform an automatic cleaning cycle once the analysis cycles have reached the programmed cycle limit set in the Setup Menu (see Section 5, 4.4. Setting Autocleaning frequency , page 5-11).

When an Automatic cleaning cycle begins a message will appear on the screen.

A Manual cleaning can be requested at any time by the operator:

Manual Autoclean

Main Menu
4- Service
8- Auto Clean

4.5. End of the day rinsing

It is necessary to run a Standby/Shutdown cycle at the end of each day.

Shutdown cycle

Press the «Standby» key on the front panel

The ABX **Micros 60** performs a complete cleaning with the enzymatic detergent (Miniclean) and puts the system into a Standby mode.

The ABX **Micros 60** can then be switched «OFF» at the end of the working day or left in this Standby mode until the next working day. It also may be left in the Standby mode between long breaks during the day.

When the ABX Micros 60 is left in the standby mode, it is mandatory to perform a «STARTUP» cycle before returning to any analysis cycles

5. Results

When an analysis cycle has been complete, results are displayed and printed out according to the Setup of the Instrument.

5.1. ABX Micros 60 OS/OT8

5.1.1. Displayed Results

The Parameter results are displayed on the LCD screen once the analysis cycle is complete.

5.1.2. Identification

The sample identification can be reviewed on the LCD screen

5.1.2.1. US Mode

Sample identification review

«Results» menu
«Up» or «Down» Arrow keys

5.1.2.2. Standard Mode

Run# identification review

«Results» menu
«Up» or «Down» Arrow keys

5.1.3. Flags

The PLT flags can be reviewed on the LCD screen

PLT flag review

«Results» menu
«Up» or «Down» Arrow keys

The Last sample result run can be displayed again at any time before running the next analysis (results, identification, flags):

Last Run results review

Main Menu
1- Results
«Up» or «Down»

5.1.4. Results Printout

5.1.4.1. US Mode

RESULTS

DATE : 01/20/2006 TIME : 09:25

ID : SMITH_1234567
SEQ. # : 27
STARTUP PASSED
Plt Flags :

WBC : 10.0 10^3/ mm^3	MCV :90 μm^3
RBC : 4.90 10^6/ mm^3	MCH : 30.6 Pg
HGB : 15.0 g/dl	MCHC : 34.1 g/dl
HCT : 43.9 %	PLT : 287 10^3/mm^3

Fig.3-1: US mode printout

Printed information is as follows:

1- The «Date» the sample was analyzed

2- The «Time» the sample was analyzed

3- The Sample «Identification» that the Operator had entered either (Manually or Barcode).

4- The «Sequence» number of the sample run

5- The Instrument «STARTUP» status.

6- The «PLT flags» if any were reported

7- The 8 Parameter CBC results with Limit flags and units.

The sequence number is updated to the number «1» each calendar day. the number increases by increments of 1 each analysis cycle sequentially. this sequential number can not be modified by the operator.

5.1.4.2. Standard Mode

RESULTS

DATE : 01/20/2006 TIME : 09:25

RUN # : 12345
SEQ. # : 27
STARTUP PASSED
Plt Flags :

WBC : 10.0 10^3/ mm^3	MCV :90 μm^3
RBC : 4.90 10^6/ mm^3	MCH : 30.6 Pg
HGB : 15.0 g/dl	MCHC : 34.1 g/dl
HCT : 43.9 %	PLT : 287 10^3/mm^3

Printed information printed is as followed:

1- The «Date» the sample was analyzed

2- The «Time» the sample was analyzed

3- The Sample «RUN #» that was entered by the Operator

4- The «Sequence» number of the sample run

5- The «PLT flags» if any were reported

6- The 8 Parameter CBC results with Limit flags and units.

The sequence number is updated to the number «1» each calendar day. the number increases by increments of 1 each analysis cycle sequentially. this sequential number can not be modified by the operator.

5.2. ABX Micros 60 OS/OT16

5.2.1. Displayed Results

The first group of Parameter results are as displayed on the LCD screen once the analysis cycle is complete. The second group of parameter results can be displayed as follows:

Parameter results review
«RESULTS» menu
«Up» or «Down» Arrow keys

5.2.2. Identification

The sample identification can be reviewed on the LCD screen

5.2.2.1. US Mode

Sample identification review
«RESULTS» menu
«Up» or «Down» Arrow keys

5.2.2.2. Standard Mode

Run# identification review
«RESULTS» menu
«Up» or «Down» Arrow keys

5.2.3. Flags

The PLT and WBC flags can be reviewed on the LCD screen:

PLT and WBC flags review
«RESULTS» menu
«Up» or «Down» Arrow keys

5.2.4. Result printout (US mode example)

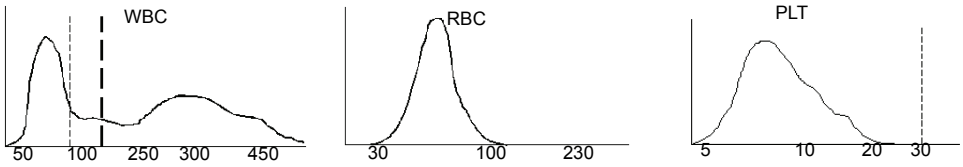
RESULTS

DATE : 01/20/2002 TIME : 09:25
ID : SMITH_1234567
SEQ. # : 27
STARTUP PASSED
PLT Flags :

WBC :	7.5 10^3/ mm^3	(3.5-10.0)	MCV	90 μm^3	(80-100)
RBC :	4.90 10^6/ mm^3	(3.80-5.80)	MCH	30.6 Pg	(26.5-35.5)
HGB :	15.0 g/dl	(11.0-16.5)	MCHC	34.1 g/dl	(31.5-33.5)
HCT :	43.9 %	(35.0-50.0)	RDW	13.0 %	(11.0-16.0)
PLT :	287 10^3/ mm^3	(150-390)	MPV	8.8 μm^3	(6.5-11.0)

WBC Flags :

%LYM :	39.3 %	(20.0-45.0)	#LYM	2.2 10^3/ mm^3	(1.2-3.2)
%MON :	7.3 %	(4.0-10.0)	#MON	0.4 10^3/ mm^3	(0.3-0.8)
%GRA :	53.4 %	(43.0-76.0)	#GRA	3.0 10^3/ mm^3	(1.2-6.8)



Printed information printed is as followed:

1- The «Date» the sample was analyzed

2- The «Time» the sample was analyzed

3- The Sample «Identification» that was entered by the Operator (Run# if Standard mode)

4- The «Sequence» number of the sample run

5- The Instrument «STARTUP» status (none in Standard mode)

6- The «PLT flags» if any were reported

7- The 16 Parameter CBC results with limit flags and units.

8- The «WBC flags» if any were reported

9- The 3 part Differential LMG results

10- The WBC, RBC, and PLT Histograms.

The sequence number is updated to the number «1» each calendar day. the number increases by increments of 1 each analysis cycle sequentially. this sequential number can not be modified by the operator.

5.3. ABX Micros 60 OS/OT18

The ABX Micros 60 OS/OT18 has all the same characteristics as the ABX Micros 60 OS/OT16 with the exception of 2 parameters, PCT and PDW which are reported on the ABX Micros 60 OS/OT18 results

6. Flags

These Instrument flags and alarms can be classified in 3 different groups:

1- Results exceeding normal limits: See "6.1. Normal Limits, page 15".

2- Flags linked to results that exceed the linear range of the instrument or leading to «Rejected Analysis» See "6.2. Flags causing analysis reject, page 15"

3- Flags and alarms linked to the morphology of a blood cell population See "6.3. Morphology Flags , page 17"

6.1. Normal Limits

- The «**H**» flag located next to a parameter result indicates that the value is «Above»the Upper limit set by the operator. Section 5, 3. Laboratory Limits , page 5-7
- The «**L**» flag located next to a parameter result indicates that the value is «Below» the Lower limit set by the operator.

6.2. Flags causing analysis reject

These flags are shown in different ways as indicated:

- "6.2.1. Results Exceeding Linear range , page 15"
- Results associated with an Asterisk (*): "6.2.2. Results Rejected , page 16"
- ,Dollar sign ($): "6.2.3. Results Comparable , page 16"
- or Exclamation mark for HGB (!): "6.2.4. HGB Blank Reference , page 16"

6.2.1. Results Exceeding Linear range

Tab.3-1: Displayed results on screen

Parameters	Linearity limits	Visible Range	> Visible Range
WBC($x10^3/mm^3$)	«result»	«result»+ «D»	DIL
RBC($x10^6$ /mm^3)	«result»	«result»+ «D»	DIL
PLT($x10^3/mm^3$) $_{HGB\geq 2g/dL}$	«result»	«result»+ «D»	DIL
PLT($x10^3/mm^3$) $_{HGB<2g/dL}$	«result»	«result»+ «D»	DIL
HGB(g/dL)	«result»	«result»+ «D»	DIL
HCT(%)	«result»	«result»+ «D»	DIL

Tab.3-2: Printed and host transmitted results

Parameters	Linearity limits	Visible Range	> Visible Range
WBC($x10^3/mm^3$)	«result»	«result»+ «D»	--.-- + D --.-- + 0
RBC($x10^6$ /mm^3)	«result»	«result»+ «D»	--.-- + D --.-- + 0
PLT($x10^3/mm^3$) $_{HGB\geq 2g/dL}$	«result»	«result»+ «D»	--.-- + D --.-- + 0
PLT($x10^3/mm^3$) $_{HGB<2g/dL}$	«result»	«result»+ «D»	--.-- + D --.-- + 0
HGB(g/dL)	«result»	«result»+ «D»	--.-- + D --.-- + 0
HCT(%)	«result»	«result»+ «D»	--.-- + D --.-- + 0

Whole Blood parameter results within visible range will still give a result value with a «D» indication. These results require a dilution (or PRP analysis for PLT) of the sample.

6.2.2. Results Rejected

A «Reject» flag, shown by an asterisk (*) following the Parameters WBC, RBC, HCT, or PLT indicates that the ABX Micros 60 has analyzed that parameter for a maximum of 3 counts. All 3 counts were outside the system precision limits for that specific parameter.

The results should be verified by re-running the sample.

6.2.3. Results Comparable

A reportable result shown by a Dollar sign ($) following the parameters WBC, RBC, HCT, or PLT indicates that the ABX Micros 60 has analyzed that parameter for a maximum of 3 counts. Two out of three counts were within the system precision limits for that specific parameter. The results can be reported, but the parameter should be monitored for the next sample analyzed.

6.2.4. HGB Blank Reference

A suspicious flag, shown by an Exclamation (!) located next to the Hemoglobin result shows that the HGB Blank carried out during the analysis differs from the previous cycle's HGB Blank. This (!) means that both HGB blanks were outside the Instrument precision limits.

This result can be reported, but the parameter should be monitored for the next sample analyzed.

The MCH and MCHC may also be affected by this (!) flag depending on the severity of the results.

If the Exclamation (!) flag occurs more than 3 consecutive sample runs, troubleshoot the HGB parameter in the following section of this manual. Section 6, 2. Troubleshooting, page 6-17.

6.3. Morphology Flags

6.3.1. Flags on PLT Distribution curve

The PLT Histogram has 128 channels between 2fl and 30fl. A mobile Threshold (Positioned to 25fl by default) moves according to the Microcyte population present in the Platelet analysis area.

The PLT flags are as followed:

1- An excessive presences of cells to the right of the Threshold area (25fl) will trigger the «**MIC**» (Microcytes) flag. The Mobile threshold looks for a valley between the (25fl standard value) and 18fl.

2- When there is No valley between PLT and RBC populations, a reject PLT (*****) flag is triggered. PLT results are not reliable and must be verified by a Manual Platelet Count.

3- If the number of particles between 18fl and 25fl are too high, the «**SCH**» (Schizocytes) flag will be triggered. Suspected abnormalities include:

- Presence of Schizocytes
- Presence of Platelet aggregates: Verify the Platelet results on a stained blood smear.

4- The «**SCL**» (Small cells) flag indicates the presence of small cells in the 2fl to 3fl zone. The PLT results may be reported as (---) and there may also be no PLT Histogram.

6.3.2. Flags on WBC Distribution curve

The ABX **Micros 60** 0S/0T16 and 0S/0S18 has a system of WBC Differential flags alerting the operator to the possible presence of pathological cells, abnormal volume distribution histograms, or abnormal elevated populations such as the excessive presence of Eosinophils and Basophils.

1- Flag «**L1**» indicates an abnormal number of cells, in comparison with the Lymphocytes, in the 30fl to 60fl zone. The pathological elements which may be found in this area include:

- Platelet aggregates
- Nucleated Red blood cells

This flag corresponds to the number of cells counted in the first (5) channels, out of the total number of Lymphocytes.

2- The «**M2**» flag indicates an excessive number of cells in the (130fl to 160fl zone). The Pathological elements which may be found in this area will include:

- Lymphoblasts
- Myelocytes
- Atypical Lymphocytes
- Basophilia (too many basophils)

This flag corresponds to the number of cells counted in the detection zone in comparison to the total number of Monocytes.

3- The «**G1**» flag indicates an excessive number of cells in the (160fl to 220fl zone). The pathological elements which may be found in this area will include:

- Eosinophilia (too many Eosinophils)
- Myelocytes
- Neutrophil polynucleose

This flag corresponds to the number of cells counted in the detection zone in comparison to the total number of Granulocytes.

4- The «**G2**» flag indicates an excessive number of cells in the (220fl to 250fl zone). This flag makes it possible to follow an abnormal Granulocyte peak displacement. Some of the cell variances will include:

- Anomalies in the cell membrane of the Granulocytes
- Possible Lyse flow error
- Fluidic errors
- Old blood (after 6 to 8 hours) unrefrigerated
- Granulocyte cell size less than 250fl.

5- The «**G3**» flag indicates an excessive number of cells larger than 400fl. The pathological elements which may be found in this area will include:

- Metamyelocytes
- Many types of Large Immature Cells

This flag corresponds to the number of cells counted in the detection zone in comparison to the total number of Granulocytes. This cell count will be higher than the set level.

All Anomalies and/or Abnormal distribution flags given by the ABX Micros 60 should be Manually verified by the examination of a stained peripheral blood smear for the presence of pathological elements. As a result of the differential resistance of cytoplasmic membranes in the different cell types, pathological elements can be found in a number of different zones. This also applies to presence of Normal or non-pathological cells that have been subjected to Chemotherapy or some other form of treatment which affects the alarm zones. These types of treatments will result in «False» alarms.

Contents

1. Quality Control 4-2
1.1. Functions 4-2
1.2. Q.C - Automatic (With Q.C. Smart Card) 4-2
1.2.1. QC Smart card messages 4-3
1.2.2. Select Operator 4-3
1.2.3. Select commercial control level 4-3
1.2.4. Running Control blood 4-4
1.2.5. QC results 4-5
1.2.6. Accepting or Rejecting QC Results 4-5
1.3. Q.C. Analysis (Without Q.C. Smart Card) 4-7
1.4. Q.C. print targets (only with Q.C. smart card) 4-7
1.5. Q.C. statistics (only with Q.C. smart card) 4-8
1.6. Q.C. Graphs (Only with Q.C. smart card) 4-9
2. Calibration 4-11
2.1. General recommendations 4-11
2.1.1. Preliminaries 4-11
2.1.2. Calibration procedure 4-11
2.2. Calibration function 4-11
2.2.1. Change lot number 4-12
2.2.2. Change Expiration date 4-12
2.2.3. Changing the target value 4-12
2.2.4. Change number of calibration samples 4-12
2.2.5. Running calibrator 4-13
2.2.6. Calibration Results 4-13
2.2.7. Verify Calibration 4-14
2.2.8. Calibration Passed 4-15
2.2.9. Calibration Failed 4-16
2.2.10. RDW Calibration 4-17
2.2.11. RDW calibration using a Quality Control Standard 4-17
2.2.12. Calibration coefficients 4-18
2.2.13. Changing Calibration Coefficients 4-18
2.2.14. Calibration Coefficient limits 4-19

1. Quality Control

1.1. Functions

It is highly recommended that you use the ABX MINOTROL Quality Control blood product when running Q.C. on the ABX Micros 60 analyzer. This product is specifically designed for use with the ABX Micros 60 analyzers. Call your local HORIBA Medical Customer Service Representative for information and ordering of this specialized product.

The ABX Micros 60 0S/0T Quality Control program contains 5 different functions in its menu:

Quality Control overview

1- **Automatic**: to analyze commercial control bloods and store results on the Quality Control smart card (see"1.2. Q.C - Automatic (With Q.C. Smart Card) , page 2")
2- **Analysis:** to analyze commercial control blood with fixed WBC Thresholds specifically for use «Without» a Smart Card (see "1.3. Q.C. Analysis (Without Q.C. Smart Card) , page 7")
3- **Print Targets**: to print QC product target values fromthe QC Smart Card «Only» (see "1.4. Q.C. print targets (only with Q.C. smart card) , page 8")
4- **Statistics**: to print the cumulative statistics for commercial control bloods from the QC Smart Card «Only» (see "1.5. Q.C. statistics (only with Q.C. smart card) , page 8")
5- **Graphs**: to print the Levey Jennings graphs of the commercial Control blood products from the QC Smart Card «Only» (see "1.6. Q.C. Graphs (Only with Q.C. smart card) , page 9")

When running Quality Control «Without» the use of a Smart Card, pay close attention to the Result parameter Limits, if the system was programmed to print out the limits. These limits «Are not» Quality Control limits. These limits are the ones that were established in the setup menu «See Section 5, 3. Laboratory Limits , page 5-7». Verify your control results with the Assay sheet that comes with the control material. Verify that each Control level parameter is within its assayed limits!

1.2. Q.C - Automatic (With Q.C. Smart Card)

1- Remove the Quality Control blood from the refrigerator and bring it to room temperature.

Entering QC Automatic

Main Menu
2- QC
1- Automatic

This menu will move the operator through the automatic quality control process once the Smart Card is inserted. Operator selection, Lot # identification, Expiration date, ...etc. will be displayed between each step of the process.

2- Insert the Quality Control Smart Card into the card reader with a firm push until you hear it «click» into place.

The ABX Micros 60 will only accept the Quality Control Smart Card while in the Q.C. program! It will not accept:
1 - A Q.C. card that has expired
2 - A Memory Card
If you have the correct card and have error messages, contact your local HORIBA Medical Technical Support Representative for further instructions regarding this issue.

The ABX **Micros 60** will automatically read the card and display the Lot # and Expiration date of the current card.

It is mandatory to verify that the Quality Control Smart card being used matches the instrument type (ABX Micros 60) the Lot #, and expiration date of the Quality Control material being used for this program!

1.2.1. QC Smart card messages

«**NO SMART CARD... INSERT NEW CARD**»: means that card has not been inserted, or incorrectly, or there is technical failure with the reader.

«**NEW QC**» means that this card is being used for the very first time.

«**XX QC RUN**» When the card already has Q.C. data on it, the display will show the next sample run for Quality control, i.e. 18 QC RUN inplace of new QC. This number indicates the next Q.C. run after the stored runs.

For example: 1 complete QC RUN contains all 3 levels of controls, Low, Normal, and High analyzed 1 time each.

«**QC DIFF**» means that there is a difference between the QC index in the ABX **Micros 60** and the QC index on the QC Smart card. This usually occurs when there is confusion between 2 QC Smart cards. If the operator presses the «Enter» key, the analyzer accepts the differences and automatically equals the indexes. If the operator presses the «Esc» key, the analyzer requests a new card, reads the new card information, and displays it.

«**SMART CARD FULL**» means that the QC Smart Card has reached its limit on stored QC data and cannot store anymore on that specific card. A Maximum of 33 QC runs can be stored on QC Smart Card. 1 complete QC RUN contains all 3 levels of controls, Low, Normal, and High, analyzed 1 time each. When the card is full, you must insert a New Card and press the «Enter» key to accept the new card information.

1.2.2. Select Operator

Once you have accepted the QC Smart card information, the display will prompt you to select an Operator (OP):

Selecting operator
«Up» & «Down» arrow key to select one of 4 operators.
Press «Enter» key: The chosen operator is shown by a star (*).

1.2.3. Select commercial control level

Select level of commercial control you would like to analyze first. The display is as indicated:

Selecting Level
«Up» & «Down» arrow key to select one of 3 levels (Low, Normal or High).
Press «Enter» key to accept this level.

A message «**LOADING LEVEL PLEASE WAIT**» will be displayed. The information on the QC Smart card is read at this time.

After the information is read off of the card, ABX **Micros 60** will ask if you want to run the level of commercial control selected as indicated on the display.

1.2.4. Running Control blood

3- Verify that the lot number on the screen matches the lot # on the Commercial control blood.

4- Once the Control blood has equilibrated to room temperature, Gently and thoroughly mix the level. Follow the product instructions that come with the control kit for proper mixing.

5- Remove the cap and place the vial beneath the sample probe, raise the vial upwards so that the sample probe enters into the blood.

6- Press the «Start» key (or the Manual Sample Bar) on the front panel to start the cycle.

1.2.5. QC results

When the control analysis cycle is complete, the results are displayed.

QC results review

Use the «Up» and «Down» arrow keys to scroll through the results.

The control results are printed out as indicated:

QC

DATE : 01/20/2006 TIME : 09:25
LOT # : M211 LOW
EXP DATE : 03/20/2006
OPERATOR : OP. 1 Q.C. : 02
SEQ. # : 1
STARTUP PASSED

WBC :	2.3 10^3/mm^3	(1.7 - 2.5)	MCV :	67 µm^3	(63 - 71)
RBC :	2.36 10^6/mm^3	(2.27 - 2.57)	MCH :	23.6 Pg	(23.6 - 27.6)
HGB :	5.6 **L** g/dl	(5.7 - 6.7)	MCHC :	35.2 g/dl	(35.2 - 41.2)
HCT :	15.9 %	(14.2 - 18.2)	RDW :	12.7 %	(9.9 - 15.9)
PLT :	70 10^3/ mm^3	(52 - 92)	MPV :	9.4 µm^3	(7.4 - 11.4)
DIFF :					
%LYM :	59.6 %	(52.7 - 66.7)	#LYM :	1.3 10^3/ mm^3	(0.9 - 1.7)
%MON :	14.2 %	(7.4 - 19.4)	#MON :	0.3 10^3/ mm^3	(0.1 - 0.5)
%GRA :	26.2 %	(19.9 - 33.9)	#GRA :	0.7 10^3/ mm^3	(0.2 - 1.0)

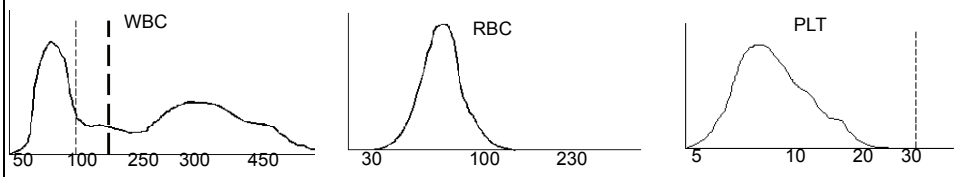


Fig.4-1: QC results printout

Printed results may vary on the amount of data displayed on the printout. Limits, LMG's, histograms, and parameters are all dependant upon the initial instrument setup. See Section 5, 2.7. Print LMG Results **, page 5-6S.**

1.2.6. Accepting or Rejecting QC Results

The results from the control blood are compared to Assayed ranges stored on the Quality Control smart card:

- If any of the parameter results are «Out of Range», an «**H**»(High) or «**L**»(Low) will be shown on the display and on the printout as well.

◆If a third counting sequence is initiated during the analysis cycle, and a specific parameter is in question, a dollar sign (**$**) or a star (*****) will be shown on the display next to the parameter and the run will automatically be Rejected. You «MUST» rerun the control blood if the display indicates: «RUN REJECTED. PRESS A KEY TO CONTINUE»

◆If the HGB Blank is not within acceptable limits, an Exclamation (**!**) is displayed next to HGB and the run will automatically be rejected.

1.2.6.1. Accepting results

Accepting QC results

Results are within acceptable limits
No alarm has been triggered out
Press the «Esc» key
«Valid Low?» is displayed
Press «Enter» key to valid.

If the operator «Accepts» the results by pressing the «Enter» key, they will be stored on the QC Smart card and the display will return to SELECT LEVEL as described in "1.2.3. Select commercial control level , page 3". Use the «Up» or «Down» arrow keys to select the next control level for analysis.

7- Once the next level has been selected, Press the «Enter» key to load that control level.

8- Gently and thoroughly mix the next control level blood. Repeat steps "5" through " Accepting QC results, page 6".

9- After accepting the second control level results, the ABX **Micros 60** automatically loads the last control level without returning to the SELECT LEVEL display.

10- Gently and thoroughly mix the next control level blood. Repeat steps "5" through " Accepting QC results, page 6".

11- Once the last control level has been accepted, the display will indicate:

Storing QC results

«Valid QC?» message is displayed
Press «Enter» key
«QC Stored» message is displayed
Press the «Esc» key to exit QC menu

If the QC is accepted and validated, the index is increased on the QC Smart card and the ABX **Micros 60** internal index is increased as well.

1.2.6.2. Rejecting Results

Error flags such as (H, L,*, $, and ! for HGB) on control results are NON-valid results! The parameters with these specific flags should be reviewed and questioned before continuing with the next level of control blood.

Accepting QC results

Results are not within acceptable limits
Alarms have been triggered out
Press the «Esc» key
«Valid Low?» is displayed
Press the «Esc» key to reject.

you have the option of re-running that same control level again or selecting another level. No results will be stored on the QC smart card.

1.2.6.3. Exiting Q.C. Automatic

If the operator needs to Exit Q.C. at any time before all levels of control bloods are analyzed, it is possible to do so by following these simple steps:

1- Wait until the cycle of the control level blood being analyzed is complete.

Exiting QC automatic

Press the «Esc» key
«Valid?» message is displayed
Press the «Esc» key
The display returns to «Start QC» message
Press the «Esc» key
«Exit QC?» message is displayed
Press the «Enter» key
«QC not valid» message is displayed (QC not stored on the Smart card)
The display returns to the QC menu.

1.3. Q.C. Analysis (Without Q.C. Smart Card)

1- Remove the Quality Control blood from the refrigerator and bring it to room temperature.

Entering QC

Main Menu
2- QC
2- Analysis

This menu will allow the operator to run a control level blood as a normal analysis cycle «Without» the use of a Smart Card, but with specific LMG Thresholds for control level bloods. (Independant from the Temperature)

Identification of the control blood

«Lot#:_» message is displayed
Enter a Lot number (from 1 to 10 Alphanumeric characters). Use the Number keys to enter the numbers directly. Use the «Up» or «Down» arrow keys to select each Alpha character, Press «Enter» key after each Alpha entry.
Press the «Enter» key to accept it.

A brief HGB Blank reference measurement is performed before the analysis cycle. When the HGB Blank reference measurement is complete, a message indicates to start the analysis.

2- Once the Control blood has equilibrated to room temperature, Gently and thoroughly mix the level of control blood to be analyzed . Follow the product instructions that come with the control kit for proper mixing.

3- Remove the cap and place the vial beneath the sample probe, raise the vial upwards so that the sample probe enters into the blood.

4- Press the «Start» key (or the Manual Sample Bar) on the front panel to start the cycle.

When the analysis cycle is complete, the results are displayed and printed out as shown "Fig.4-1: QC results printout, page 5".

1.4. Q.C. print targets (only with Q.C. smart card)

This Q.C. sub-menu allows you to print out the Assay ranges of all 3 levels of control blood from the Q.C. Smart Card.

1- Insert the Q.C. Smart Card into the reader with a firm push until it «clicks» into place.

Printing targets
Main Menu
2- QC
3- Print targets
«Lot#» and «Exp Date» are displayed
Press «Enter» key

The printout will show Low limit and High limit for each parameter, for each assayed level of control. HIGH, NORMAL,and LOW.

1.5. Q.C. statistics (only with Q.C. smart card)

This Q.C. sub-menu allows the operator to print out all the stored cumulative data for all 3 levels on the control blood. The information printed out will contain all the necessary statistical data for each level. The levels can be selected individually or all at once.

It is highly recommended to print out all Quality Control Statistical data at the end of each month for hard copy verification of control data.

Each File printout contains the following information: File Name (Blood Level), Lot # of the Control, Expiration date of the control, Date and Time of the print data request, Date and Time of each control run, Operator and Parameter results of each control run, the Reference Assay Mean, Upper, and Lower limits, the Actual Mean results of the total control runs, the Standard Deviation value, and the Percent Coefficient of Variation.

Tab.4-1: Limits of CV on Control blood:

	Low limit	Normal limit	High limit
WBC	7%	5%	4%
RBC	4%	3%	3%
HGB	5%	4%	3%
HCT	5%	4.5%	4%
MCV	4%	3%	2.5%
RDW	5%	5%	5%
PLT	15%	10%	7%
%LYM	8%	8%	8%
%MON	15%	14%	11%
%GRA	12%	4%	3%

CV are relevant when they are calculated on at least 6 values.

Printing Statistics:

Selecting Statistics
Main Menu
2- QC
4- Statistics. Press «Enter» key
Use the «Up» & «Down» arrow key to select one of the 3 levels to be printed out
Or select «ALL» to print out the 3 levels (a star * shows the current selection)
Press «Enter» key to print out the statistical data

Maintain a copy of these results each month for Quality Control Analysis verification.

Q.C.

NORMAL

LOT#: M211 TIME: 07:31

EXP DATE :02/20/06 DATE: 03/19/06

No	DATE	TIME	OP	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
1	01/20/06	09:57	OP. 2	7.4	4.58	13.6	36.3	79	29.7	37.5	279
2	01/21/06	08:23	OP. 1	7.3	4.52	13.2	35.3	78	29.2	37.4	247
3	01/22/06	10:57	OP. 3	7.3	4.47	13.4	35.2	79	29.9	38.0	254
--	---------	------	------	----	-----	-----	-----	----	-----	-----	-----
--	---------	------	------	----	-----	-----	-----	----	-----	-----	-----

ETC.....

REFERENCE:

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	7.4	4.52	13.4	35.7	79	29.6	37.5	249
LOW	6.8	4.34	12.8	33.7	75	27.6	34.5	219
HIGH	8.0	4.70	14.0	37.7	83	31.6	40.5	279

ACTUAL:

	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	PLT
MEAN	7.4	4.54	13.3	35.5	78	29.4	37.5	252
SD	0.13	0.06	0.16	0.59	0.63	0.43	0.53	11.22
CV	1.70	1.37	1.18	1.67	0.80	1.46	1.40	4.45

ETC...

Fig.4-2: QC Statistics printout

1.6. Q.C. Graphs (Only with Q.C. smart card)

The ABX **Micros 60** plots Levey-Jennings charts for each parameter of the Quality Control files stored on the Q.C. Smart card. Each Levey-Jennings chart will plot 1 data point per parameter, per control run, for every control data point stored.

Printing Graphs:

Selecting Graphs

Main Menu
2- QC
5- Graphs. Press «Enter» key
Use the «Up» & «Down» arrow key to select one of the 3 levels
Or select «ALL» to select the 3 Levels
Press «Enter» key to printout the Graphs

The parameter charts are determined by the internal software setup. See Section 1, 1.1. Parameters, page 1-3 for the parameters that are printed out on the Levey-Jennings charts.

Levey-Jennings charts are printed out with the following information included: File Name (Blood Level), Lot # of the Control, Expiration date of the control, Date and Time of the print data request, the Parameter Name, and the Parameter graph with 40 total data points. Below each graph, the Reference Assay Mean, Upper, and Lower limits, the Actual Mean results of the total control runs, the Standard Deviation value, and the Percent Coefficient of Variation.

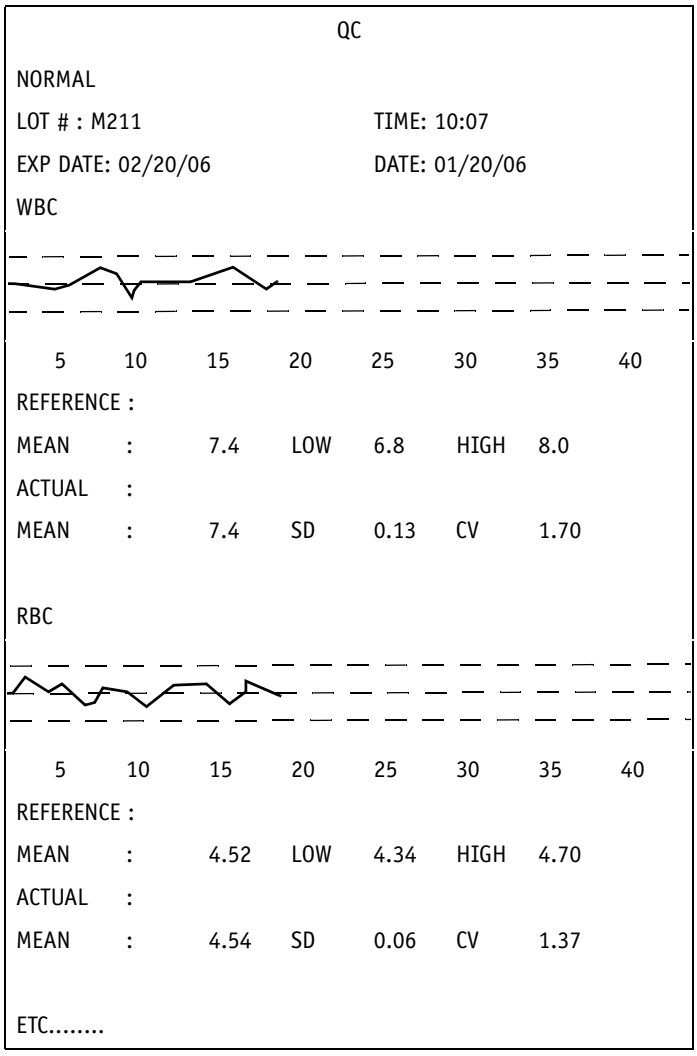


Fig.4-3: QC Graphs printout

2. Calibration

2.1. General recommendations

The calibration on **HORIBA Medical** instruments is an exceptional procedure, which must be carried out particularly in case of certain technical interventions (installation, maintenance, service intervention). The calibration should not be carried out to compensate a drift on a result due for example to a clogging of the instrument.

2.1.1. Preliminaries

Before carrying out a calibration, it is essential to make sure that the instrument is in perfect condition of operation, and to follow the following steps:

1- Carry out a Concentrated cleaning procedure (See Section 6, 1.3.6. Concentrated Cleaning, page 6-11).

2- Perform two blank cycles to check the cleanliness of the instrument.

3- Check the repeatability of the instrument by running a fresh normal whole blood sample 11 times with no alarms. Discard the first result and calculate the CV on the remaining 10 runs.

4- Check that the CV calculated using the remaining 10 runs meets or exceeds the specifications in "3.2. Precision Claims*, page 9"

5- Run a control blood and check that the values are within the acceptable limits. If not, run a new control blood.

If the values are still out of the acceptable limits and instrument is clean (blank cycles in conformity with the values given in the manual) and repeatability is correct (Acceptable CV values), carry out the calibration as described in "2.1.2. Calibration procedure, page 11".

2.1.2. Calibration procedure

1- Run at least 4 times Calibrator without taking the values of the first result into account (see "2.2.5. Running calibrator , page 13").

2- Calibrate the instrument on the average of the last three results according to indications of the manual, see "2.2.8. Calibration Passed , page 15"

3- Run 3 times again Calibrator to check the values.

4- Confirm the calibration while passing a control blood, the values have to be returned within acceptable limits.

5- After about thirty numerations analyses of the day, check that values of MCV, MCH and MCHC are in conformity with the usual values of the laboratory.

2.2. Calibration function

The ABX **Micros 60** Calibration can be achieved in 2 different ways.

1- Calibration is performed using a Calibrator Blood sample.

2- Known Calibration Coefficients can be directly entered by selecting a Calibration Menu option.

Accessing the calibration function

Main Menu
3- Calibration
1- Autocalibration
Select one of the 4 operators (O.P) defined in Section 5, 4.1. Changing Operator , page 5-10
Press «Enter» Key

2.2.1. Change lot number

From the previous screen (See "2.2. Calibration function, page 11") proceed as follows to change the calibrator lot number:

Changing lot number

«Insert new card» message is displayed
Press the «Esc» key in order to edit all the calibration information Manually.
Press the «Enter» key to enter the new lot number of the calibrator material.
«Lot# ?» message is displayed
Enter the new «Lot#» of the current calibrator
Use the «Up» and «Down» arrow keys to enter the Alpha characters.
Use the Numeric keys to enter the Numbers.
Press the «Enter» key to save the new lot number

2.2.2. Change Expiration date

From the previous screen (See "2.2.1. Change lot number, page 12") proceed as follows to modify the Expiration date:

Changing Expiration date

«Change Exp date?» message is displayed
Press the «Enter» key
Enter the new expiration date from the Calibration Assay sheet.
Use the arrow keys after entering the Month.
Use the arrows key after the Day.
Press the «Enter» key to save the new expiration date

2.2.3. Changing the target value

From the previous screen (See "2.2.2. Change Expiration date, page 12") proceed as follows to modify the target values:

Changing target values

«Change target WBC?» message is displayed
Press the «Enter» key
Enter the new target value for WBC from the Calibration Assay sheet.
Press the «Enter» key to save and move to the next entry

The next screen will indicate changing the RBC target value. Repeat the same steps for RBC, HGB, HCT, PLT, and MPV.

2.2.4. Change number of calibration samples

From the previous screen (See "2.2.3. Changing the target value, page 12") proceed as follows to modify the number of samples to be run for calibration:

Changing sample number

«Change sample # ?» message is displayed
Press the «Enter» key
Enter the number of samples you wish to run for calibration or press the «Esc» key.

The number of samples you can run for calibration is a Minimum of 3 and a Maximum of 11. In order for the instrument to provide the best mathematical data for a good calibration, a Minimum of 6 sample runs is highly recommended for quality statistical calibration data.

2.2.5. Running calibrator

From the previous screen (See "2.2.4. Change number of calibration samples , page 12") proceed as follows to run an analysis on calibrator:

Running calibrator sample

«Run Cal ?» message is displayed
Press the «Enter» key (a prime cycle is launched first)

1- Now gently and thoroughly mix the Calibrator material as indicated on the Instruction sheet that comes with the calibrator.

2- Place the calibrator beneath the sample probe, and raise the vial upwards so that the sample probe enters into the blood.

3- Press the «Start» key on the front panel to initiate the cycle of the first sample, or press the manual sample bar. The cycle will begin and the sample will be aspirated.

Wipe any excess blood from the cap and threads of the calibrator vial with a lint-free tissue to prevent any dried blood from reentering into the calibrator material. Dried Blood re-entering into the vial may give error flags and reject the sample runs.

2.2.6. Calibration Results

Validating results

Verify that the results are within 20% of each parameter target value.
Press the «Enter» key to continue.
«Valid calibration #1/6» message is displayed
Press «Enter» to valid («Esc» to reject and to return to the first run)
«Start calibration #2/6» message is displayed

Calibration results having Error flags such as ($, *, or ! for HGB) will automatically be rejected! The system will automatically re-set itself to rerun that sample. If you acquire 3 rejects continuously on the same number sample, abort calibration and contact your local HORIBA Medical Technical Support representative!

4- Place the cap back onto the vial, gently and thoroughly mix the material for the next calibration sample run.

5- Run the remaining calibrator samples, as described in "2.2.5. Running calibrator , page 13".

When the last sample result has been validated, the ABX **Micros 60** calculates the statistical calibration factors for each parameter. These statistical calculations include the Mean, Target, Coefficient of Variation, Percent difference between the Target value and the Mean, Previous Calibration coefficients, and the New Calibration Coefficients. The Status will indicate on the printout if a parameter has **Passed** or **Failed** Calibration.

2.2.7. Verify Calibration

1- Once the calibration is complete and has Passed the Calibration criteria, Press the «Esc» key until you have returned to the Main Menu.

2- Run the remaining Calibrator material 3 times as a regular patient analysis. (Remember to gently and thoroughly mix the material between each sample run.)

3- When each cycle is complete, record the results. Calculate the Total and Mean values for each parameter listed. Now compare the Mean value for each parameter to the Assay Mean values and ranges listed for the ABX Micros 60. Verify that all the calculated parameters fall within the specific parameter Ranges on the Assay sheet. If all parameters are within their specified ranges, Calibration is complete.

4- Run Quality Control and verify that all 3 levels of control results are within their specified ranges. Verify that all control parameter results are without Flags (H, L, *, $, and ! for HGB).

2.2.8. Calibration Passed

In order for ABX Micros 60 to «Pass» Calibration, the data must meet the statistical criteria which contain 2 conditions.

1- The Coefficient of Variations must be within their limits as indicated "Tab.4-2: Coefficient of variation limits, page 15".

2- The difference between the «Target value» and the «Mean» for each parameter calibrated, must be less than 20%.

Tab.4-2: Coefficient of variation limits

Parameters	WBC	RBC	HGB	HCT	PLT	MPV
CV%	< 2.5	< 2.0	< 1.5	< 2.0	< 5.0	< 3.0

«Passed» calibration is as follows:

CALIBRATION

DATE : 01/20/2006 TIME : 09:48

OPERATOR : ABC

LOT # : MCAL212

RUN	WBC	RBC	HGB	HCT	PLT	MPV
1 P	10.2	4.50	14.0	38.0	242	7.6
2	9.9	4.45	14.0	37.4	246	7.9
3	9.7	4.41	14.0	37.2	237	7.7
4	10.0	4.51	14.2	37.9	251	7.7
5	9.9	4.43	14.1	37.2	254	7.5
6	9.8	4.38	14.1	36.8	248	7.5
MEAN	9.9	4.44	14.1	37.3	247	7.7
TARGET	9.9	4.54	13.5	37.2	260	7.7
CV	1.0	1.0	0.7	1.0	2.3	1.8
% CHG	0.0	2.25	5.74	0.73	5.26	0.0
OLD CAL.	1.09	0.89	1.11	1.08	1.20	0.94
CURRENT	1.09	0.91	1.07	1.08	1.26	0.94
STATUS	OK	OK	OK	OK	OK	OK

Fig.4-4: Passed Calibration printout

The «P» to the right of RUN # 1 indicates that the first calibration sample is not included in the statistical calculations. This first sample is considered as a Calibrator material prime.

The instrument wait for the operator to press any key to return to the MAIN MENU.

2.2.9. Calibration Failed

In order for ABX Micros 60 to «Fail» Calibration, the data must meet the statistical criteria which contain 2 conditions.

1- The Coefficient of Variations are out of thier specified limits as indicated in "Tab.4-2: Coefficient of variation limits, page 15".

2- The difference between the «Target value» and the «Mean» for each parameter that failed calibration, is greater than 20%.

When ABX Micros 60 «Fails calibration», the results will be printed out, the Calibration coefficients are «Rejected», and the previous coefficients will remain unchanged in memory and the screen will indicate: «CALIBRATION FAILED !»

When the Calibration STATUS indicates «FAILED» on one or more parameters, even though stating «OK» on the other parameters, Calibration will not take place. When the calibration fails, the operator may restart the calibration again or call your local HORIBA Medical Technical Support representative for further instructions.

On the screen display: Rejected and saved coefficients can be displayed by using the «Up» and «Down» arrow keys on the front panel. Press the «Esc» key to return to Main Menu.

«Failed» Calibration printout is as follows:

CALIBRATION

DATE : 01/20/2006 TIME : 09:48

CALIBRATION FAILED

OPERATOR : ABC

LOT # : MCAL212

RUN	WBC	RBC	HGB	HCT	PLT	MPV
1 P	10.2	4.50	14.0	38.0	242	7.6
2	9.9	4.45	14.0	37.4	246	7.9
3	9.7	4.41	14.0	37.2	237	7.7
4	10.0	4.51	14.2	37.9	251	7.7
5	9.9	3.65	14.1	31.8	254	7.5
6	9.8	4.38	14.1	36.8	248	7.5
MEAN	9.9	4.32	14.1	36.5	247	7.7
TARGET	9.9	4.54	13.5	37.2	260	7.7
CV	1.0	7.7	0.7	6.3	2.3	1.8
% CHG	0.0	5.09	5.74	1.92	5.26	0.0
REJ. COEFF	1.09	0.89	1.11	1.08	1.20	0.94
CURRENT	1.09	1.05	1.07	1.02	1.26	0.94
STATUS	OK	FAILED	OK	FAILED	OK	OK

Fig.4-5: Failed Calibration printout

2.2.10. RDW Calibration

The RDW calibration is a separate calibration outside the Auto-calibration menu.

The RDW calibration coefficient default value is normally set at 1.00.

RDW coefficient editing

Main Menu
3- Calibration
2- Coefficients
1- Calib. Coeff./ password 123 or the one defined by the operator in the setup menu.
(See Section 5, 4.2. Changing (the User) Password , page 5-10).
Press «Enter» key
Select the # 7 key or use the «Down» arrow key to select the RDW coefficient
Press «Enter» key to edit the coefficient
Enter the RDW coefficient value which has been calculated from the comparison study.
Press «Enter» key to accept the new value
Return to Main menu pressing the «Esc» key

The RDW calibration is normally performed by taking blood samples from 100 healthy, normal, and drugfree individuals. These blood samples are then analyzed on instrument that has been calibrated for RDW determination. The Mean and Standard Deviation are then calculated from that population analyzed. The same 100 samples are then analyzed on the ABX Micros 60. A population Mean is calculated and then compared to the known calculated Mean from the comparison instrument. The RDW calibration coefficient for the ABX Micros 60 is then calculated from the difference of the two Mean values.
Expected RDW values may vary with sample population and/or geographical location. it is highly recommended that each laboratory establish its own normal ranges based on the local population.

2.2.11. RDW calibration using a Quality Control Standard

The RDW may also be calibrated by using a known Quality Control Standard.

DEFINITION: A Quality Control Standard is defined as a Commercial blood product which has been specifically developed and Assayed with set parameter Target values and ranges. This product is designed to precisely measure the accuracy and linearity of the analyzer.

1- Take the controls and bring them to room temperature. Gently and thoroughly mix the control material as indicated on the instruction sheet that comes with the control kit.

2- Run the Normal Level control 6 times, as a regular patient analysis. When the cycles are complete, note only the RDW results. Write down these results for future reference use.

3- Calculate the Mean value for all 6 results and write it down for future reference use.

4- Take the Control Assay sheet that comes with the control kit and note «Only», the Normal Control Mean Assay value for RDW.

Calculate the new RDW coefficient as followed:

5- Take the Normal Control Mean Assay value for RDW, Divide it by the Mean value of the Normal control ran 6 times as a sample, times the current RDW calibration coefficient, This will equal the New RDW Calibration coefficient.

6- Proceed as described in " RDW coefficient editing, page 17" to enter this new value.

7- Now take all 3 levels of controls, LOW, NORMAL, HIGH, and run them 1 time each as a regular patient analysis. When the cycles are complete, note only the RDW results and compare them to the control Assay values for RDW, on the Assay sheet. Verify that the RDW results are somewhat close to the Mean Assay values and within the ranges as specified for all 3 Levels.

8- The RDW calibration is now complete. Be sure to monitor your RDW results and verify that they fall within your patient population.

9- Verify that Normal RDW results will be within the established ranges set in the setup menu. See Section 5, 3. Laboratory Limits , page 5-7.

Certain Pathological conditions will affect the RDW results. See (See Section 1, 4.3. Known Interfering Substances, page 1-14)

2.2.12. Calibration coefficients

The operator has the option of either «Editing» the current calibration coefficients or «Printing» the current calibration coefficients.

The ABX Micros 60 is an accurate and reliable instrument when properly maintained. Should any variation of Quality Control results outside the Assayed ranges occur after calibration, it is Highly suggested that you contact your local HORIBA Medical Technical Support Representative before Manually editing the calibration coefficients!

2.2.13. Changing Calibration Coefficients

Editing calibration coefficients

Main menu
3- Calibration
2- Coefficients
1- Calib. Coeff.
Enter password 123 or the one defined by the operator in the setup menu. See Section 5, 4.2. Changing (the User) Password , page 5-10
Press «Enter» key
Press «Up» or «Down» arrow keys to select the coefficient to be edited.
Press «Enter» key and enter new coefficient derived from using the below formula:
Press «Enter» key to accept the coefficient.
Continue to use the «Up» or «Down» arrow keys to select the next coefficient to be edited.
Use the same formula below to calculate the remaining coefficients.
Press the «Esc» key until you return to the Main Menu

◆New coefficient calculation

(Parameter target value/parameter mean value) x Current parameter coeff. = New parameter coeff.

After manually editing the calibration coefficients, it is highly recommended to run Quality Control. Verify that all levels of control material are within their specified parameter ranges. Verify that there are no error flags (H, L, *, $, ! for HGB) associated with all levels of Quality control results.

Calibration Coefficients are as listed:

WBC
RBC
HGB
HCT

PLT
MPV
RDW COEFF.
PDW COEFF.

PCT and PDW are not available in the United States. These parameters are strictly used for research and investigational purposes only.

2.2.13.1. Print Coefficients

Printing calibration coefficients
Main menu
3- Calibration
2- Coefficients
2- Print Coeff.

The current calibration coefficients will automatically printout as indicated:

COEFFICIENTS

DATE : 01/20/2002 TIME : 14:26

	WBC	RBC	HGB	HCT	PLT	MPV
CURRENT	0.97	0.88	1.13	1.08	0.95	0.92

RDW COEFF : 1.00
PDW COEFF : 1.00

Fig.4-6: Calibration Coefficients printout

2.2.14. Calibration Coefficient limits

After any calibration has been performed on the ABX **Micros 60**, Verify that all parameter calibration coefficients are within their specified ranges as indicated:

Tab.4-3: Calibration Coefficient limits

Parameters	WBC	RBC	HGB	HCT	PLT	MPV	RDW	PDW
Coefficient limits								
Minimum	0.89	0.73	0.83	0.87	0.99	0.75	0.75	0.75
Target	1.09	0.89	1.11	1.08	1.20	0.94	1.00	1.00
Maximum	1.29	1.05	1.39	1.29	1.41	1.13	1.25	1.25

If any of the calibration coefficients are out of their specified ranges after calibrating the ABX **Micros 60**, contact your local **HORIBA Medical** Technical Support Representative.

Contents

1. Setup overview 5-2
2. Results Options 5-3
2.1. Reprint Results 5-3
2.2. Printout 5-4
2.3. Units 5-4
2.4. Printer Selection 5-5
2.5. Temperature Printout 5-5
2.6. Print Limits 5-6
2.7. Print LMG Results 5-6
3. Laboratory Limits 5-7
3.1. Results Low Limits 5-7
3.2. Results High Limits 5-7
3.3. Print Limits 5-8
3.4. Morphology Flag Limits 5-9
3.4.1. Platelet Flags 5-9
3.4.2. WBC flags 5-9
4. Special Functions 5-10
4.1. Changing Operator 5-10
4.2. Changing (the User) Password 5-10
4.3. Choosing Startup Cycle 5-11
4.4. Setting Autocleaning frequency 5-11
4.5. Printing Instrument Configuration 5-12
4.6. Setting buzzer cycle end 5-14
4.7. Choosing sample identification mode 5-14
5. Date and Time 5-14
5.1. Change Time 5-15
5.2. Change the Date Format 5-15
5.3. Change Date 5-15
6. Host Computer Options 5-15
6.1. Host Communications 5-16
6.2. Baud Rate 5-16
6.3. Transmission 5-16
7. Barcode Setup 5-17
8. Memory Card 5-17
8.1. Memo On / Off 5-17
8.2. Running Patient Samples 5-18
8.3. Transmission of Results 5-18
8.4. Print List 5-19
8.5. Reprint One result 5-19
8.6. Reprint All Results (TR. ALL) 5-20
8.7. Reprint From / To (TR. FROM TO) 5-20
8.8. Clear Card (Erasing All Results from the Card) 5-21

1. Setup overview

The ABX Micros 60 has several operator options in this section.

- Specific Laboratory limits (see "3. Laboratory Limits , page 7")
- Date and time formats (see "5. Date and Time , page 14")
- Results format (see "2. Results Options , page 3")
- RS 232 options (see "6. Host Computer Options , page 15")
- Special functions (see "4. Special Functions , page 10")

These options can be configured according to the operator's needs, through the «SETUP» Menu functions.

Accessing Setup Menu

Main menu
5- Setup

Menu overview

Tab.5-1: Menu\Setup overview

SETUP			
1- Results	1- Reprint results		
	2- Printout < >	1- with histo 2- without histo 3- Histo. w/o RBC	
	3- Units	1- Standard 2- SI 3- Inter 1 4- Inter 2	
	4- Printer	1- Reserved 1 2- Reserved 2 3- Reserved 3 4- Standard 5- None	
	5- Print temp. y/n		
	6- Print limits y/n		
	7- Print LMG y/n		
2- Chg lab limits	1- Low limits		
	2- High limits		
	3- Print limits		
	4- Flag limits	1- SCL 2- SCH 3- MIC 4- L1 5- M2 6- G1 7- G3	
3- Special	1- Chg OP.		
	2- Chg Password		
	3- Startup cycle	1- Auto 2- Manual	
	4- Clean Freq.0		
	5- Print Config.		
	6- Buzzer yes/no		
	7- ID mode	1- Std 2- Us	

Tab.5-1: Menu\Setup overview

4- Date Time	1- Chg time		
	2- Date format		
	3- Chg date		
5- Host options	1- Host comm.	1- Format Argos 2- Format R&D 3- Format ABX 4- TR off	
	2- Baud rate	1- 300 2- 1200 3- 2400 4- 4800 5- 9600	
	3- Transmission		
6- Barcode	Checksum y/n		
7- Memo card	Memo card off		
	Memo card on	1- Memo	
		2- transmission	1- Printer 2- Host Comp.
		3- Print list 4- Reprint one 5- Reprint all	
		6- Print from-to	1- Begin 2- End 3- Reprint results
		7- Clear card	

2. Results Options

This sub-menu will allow the operator to access and edit some of the following sub-menu functions, such as:

- Reprint the result of the last sample in the system Memory ("2.1. Reprint Results , page 3")
- To select the Histograms to printed out ("2.2. Printout , page 4")
- To select the Unit of Measurement type ("2.3. Units, page 4")
- To select the type of printer ("2.4. Printer Selection , page 5")
- To select the Temperature to be printed out ("2.5. Temperature Printout , page 5")
- To select the Patient Parameter limits to be printed out ("2.6. Print Limits , page 6")
- To select the LMG's (Lymphocytes, Monocytes, and Granulocytes) to be printed out (Available only for ABX **Micros 60**-0S/0T16 or 0S/0T18 parameter analyzers)"2.7. Print LMG Results , page 6"

2.1. Reprint Results

Reprinting last results

Main menu
5- Setup
1- Results
1- Reprint results

The ABX Micros 60 will only hold 1 result in the system memory. This result is usually the very last sample analyzed, either a patient sample or a quality control level blood only. A calibrator blood result is stored in an entirely different system format.

The last results in memory will automatically printout with the following information:

- Date and Time,
- the associated Identification,
- Sample run and Sequence Number,
- Possible flags if any,
- the Histograms (if selected in the setup).

2.2. Printout

This function will disable/enable the printout of the WBC, RBC, and PLT Histograms.

Selecting histograms for printout

Main menu
5- Setup
1- Results
2- Printout
Use «Up» or «Down» arrow key, to select one of the 3 options as follows:
1- results printed out with histograms
2- results printed out without histograms
3- results printed out without RBC histogram
Press the «Enter» key to confirm.

2.3. Units

This sub-menu allows the operator to select between 4 different Units of Measurement. These units vary from country to country and are designed for international applications.

Choosing system units

Main menu
5- Setup
1- Results
3- Units
Use «Up» or «Down» arrow key, to choose one of the 4 system units as follows:
1- Standard
2- SI
3- International 1
4- International 2
Press the «Enter» key to confirm

Available units are detailed in "Tab.5-2: System units, page 4"

Tab.5-2: System units

Parameters	Standard	SI	International 1	International 2
WBC	10^3/ mm^3	10^9/L	10^3/ mm^3	10^9/L
RBC	10^6/ mm^3	10^{12}/L	10^6/ mm^3	10^{12}/L
HGB	g/dl	mmol/L	g/dl	g/L
HCT	%	I/L	%	I/L
PLT	10^3/ mm^3	10^9/L	10^3/ mm^3	10^9/L
MCV	μm^3	fl	fl	fl
MCH	pg	fmol	pg	pg
MCHC	g/dl	mmol/L	g/dl	g/L

Tab.5-2: System units

Parameters	Standard	SI	International 1	International 2
MPV	μm^3	fl	fl	fl
LYM %	%	%	%	%
LYM #	#	#	#	#
MON %	%	%	%	%
MON #	#	#	#	#
GRA %	%	%	%	%
GRA #	#	#	#	#

2.4. Printer Selection

This sub-menu allows the selection of the printer to be used along with the ABX **Micros 60**. 4 basic different model types of printers specifically designed to operate with the ABX **Micros 60** analyzer.

Selecting printer

Main menu
5- Setup
1- Results
4- Printer
Use «Up» or «Down» arrow key, to choose one of the 5 printer as follows:
1- Reserved 1, for Epson LX series printers
2- Reserved 2, for Star printers
3- Reserved 3, for Seiko Thermal printers
4- Standard, for Citizen Dot Matrix printers
5- None, for Use with External Computers
Press the «Enter» key to confirm

The «5- None» printer selection is used for an External Computer that is specifically use as an Extended Q.C. Package or/and L.I.S. connection. This selection is also used if a printer is not going to be used in conjunction with the ABX Micros 60 analyzer.

Once the Printer type has been selected, verify that a result will print from your selection: proceed as described in "2.1. Reprint Results , page 3".

Now verify that the last result ran will transmit to the printer and printout from the printer selection previously made.

2.5. Temperature Printout

This sub-menu allows the operator to have visual confirmation of the diluent temperature displayed on the results printout.

The operating temperature of the Diluent during analysis must remain between the specified limits (18°C - 32°C) or (65°F to 85°F). Results obtained in temperatures outside these limits are questionable and may not be valid.

Printing diluent temperature

Main menu
5- Setup
1- Results
5- Print temp. y/n
Press the «Enter» key
Use the «Up» or «Down» arrow keys to select:
1- Yes, Print with Temperature
2- No, Print without Temperature
Press the «Enter» key: a (*) indicates the current state

2.6. Print Limits

This sub-menu will enable/disable the printing of the Laboratory Limits defined as described in "3. Laboratory Limits , page 7" on the results printout.

Printing Laboratory limits

Main menu
5- Setup
1- Results
6- Print Limits
Use the «Up» or «Down» arrow keys to select:
1- Yes, Print with with Limits
2- No, Print without Limits
Press the «Enter» key: a (*) indicates the current state

2.7. Print LMG Results

This sub-menu will enable/disable the printing of the 3 part Differential parameters on the results printout.

This Menu function is available «Only» on ABX Micros 60-16 and 18 parameter systems.

Printing LMG results

Main menu
5- Setup
1- Results
7- Print LMG results
Use the «Up» or «Down» arrow keys to select:
1- Yes, Print with LMG results
2- No, Print without LMG results
Press the «Enter» key: a (*) indicates the current state

3. Laboratory Limits

Laboratory Limits are commonly known as normal patient ranges. These Limits will vary with population and/or geographical location. The default limits set on the ABX **Micros 60** are based on a study of normal, healthy, and drugfree individuals. Your limits may vary based upon the applications for intended use.

Available functions in this menu:

- Changing the Low parameter Laboratory limits (see "3.1. Results Low Limits, page 7")
- Changing the High parameter Laboratory limits (see "3.2. Results High Limits , page 7")
- Printing the Current Laboratory limits (see "3.3. Print Limits, page 8")
- Changing all Morphology Flag limits (see "3.4. Morphology Flag Limits , page 9")

Changing Laboratory limits

Main menu
5- Setup
2- Chg Lab Limits
Use the «Up» or «Down» arrow keys to select either:
1- Low Limits (step to "3.1. Results Low Limits, page 7")
2- High Limits (step to "3.2. Results High Limits , page 7")

3.1. Results Low Limits

Editing Low limits

1- Low Limits
1-WBC Low
Press the «Enter» key
Enter new value. Use the key «.» for placing the decimal point in the correct order.
Press the «Enter» key
Select the next parameter to edit using «Up» or «Down» arrow key.
Repeat the same steps to modify values.
Press the «Esc» to return to the «Chg Lab Limits» Menu

3.2. Results High Limits

Editing High limits

2- High Limits
1-WBC High
Press the «Enter» key
Enter new value. Use the key «.» for placing the decimal point in the correct order.
Press the «Enter» key
Select the next parameter to edit using «Up» or «Down» arrow key.
Repeat the same steps to modify values.
Press the «Esc» to return to the «Chg Lab Limits» Menu

3.3. Print Limits

This Chg Lab Limits sub-menu allows the operator to print out the current Laboratory Limits and Morphology Flag values.

Changing Laboratory limits

Main menu
5- Setup
2- Chg Lab Limits
3- Prt Limits
Press the «Enter» Key

The current Laboratory Limits will automatically print out as shown in "Fig.5-1: Laboratory limits printout, page 8"

LIMITS

DATE : 01/20/2002 TIME : 10:54

	LOW	HIGH	
WBC	: 3.5	10.0	10^3/ mm^3
RBC	: 3.80	5.80	10^6/ mm^3
HGB	: 11.0	16.5	g/dl
HCT	: 35.0	50.0	%
MCV	: 80	97	μm^3
MCH	: 26.5	33.5	pg
MCHC	: 31.5	35.0	g/dl
PLT	: 150	390	10^3/ mm^3
MPV	: 6.5	11.0	μm^3
RDW	: 10.0	15.0	%
%LYM	: 17.0	48.0	%
%MON	: 4.0	10.0	%
%GRA	: 43.0	76.0	%
#LYM	: 1.2	3.2	10^3/ mm^3
#MON	: 0.3	0.8	10^3/ mm^3
#GRA	: 1.2	6.8	10^3/ mm^3
PLT Flags :			
SCL%	: 8.0		
SCH%	: 8.0		
MIC%	: 8.0		
WBC Flags :			
L1%	: 8.0		
M2%	: 8.0		
G1%	: 15.0		
G3%	: 8.0		

Fig.5-1: Laboratory limits printout

Verify your entries. Check each parameter to make sure that you have entered the correct number and placement of the decimal point.

PCT and PDW are not available in the United States. These parameters are strictly used for research and investigational purposes Only.

3.4. Morphology Flag Limits

The factory «default» flag values programmed on the ABX Micros 60 were set, based on a study of normal cell populations. These Default values can be adjusted to accommodate specific populations and/or geographical locations based on those specific studies. It is highly recommended to maintain the default values unless population and/or geographical location studies are known.
Numerous factors can contribute to constant Morphology flagging. If you are experiencing constant flagging, Section 6, 2.3.1. Problems on all Parameters, **page 6-19.**
Also see Section 1, 4.3. Known Interfering Substances, **page 1-14.**

This sub-menu allows the operator to adjust the Morphology flag percentages to the specific needs of the population and/or geographical location. All the Morphology flag percentages can be adjusted from 0.01% to 25.00%.

- If you «Lower» the present Default percentages of the flags, you will make the flagging criteria «More Sensitive» and may increase your flagging alarms on sample analysis.
- If you «Raise» the present Default percentages of the flags, you will make the flagging criteria «Less Sensitive» and may decrease your flagging alarms on sample analysis.

3.4.1. Platelet Flags

Factory Default adjustment values are as follows:

SCL	:	8.00
SCH	:	8.00
MIC	:	8.00

Editing Flag values (Plt and WBC)

Main menu
5- Setup
2- Chg Lab Limits
4- Flag Limits. Press the «Enter» Key
Choose the flag to edit using «Up» or «Down» arrow key
Press the «Enter» key
Enter new value. Use the key «.» for placing the decimal point in the correct order.
Press the «Enter» key
Select the next flag value to edit using «Up» or «Down» arrow key.
Repeat the same steps to modify values.
Press the «Esc» to return to the «Chg Lab Limits» Menu

3.4.2. WBC flags

Factory Default adjustment values are as

L1	:	8.00
M2	:	8.00
G1	:	15.00
G3	:	8.00

4. Special Functions

The «Special» sub-menu will allow the operator to access and edit some of the following sub-menu functions, such as:

- "4.1. Changing Operator , page 10"
- "4.2. Changing (the User) Password , page 10"
- "4.3. Choosing Startup Cycle, page 11"
- "4.4. Setting Autocleaning frequency , page 11"
- "4.5. Printing Instrument Configuration , page 12"
- "4.6. Setting buzzer cycle end , page 14"
- "4.7. Choosing sample identification mode , page 14"

4.1. Changing Operator

4 Operator Identifications are available and can be modified.

Changing operator

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
Select 1- Chg. Op. Press the «Enter» key.
Select one of any 4 operator ID's to be edited. 4 Alphanumeric characters can be typed in:
Use the «Number keys» to enter up to 4 numbers or use the «Up» or «Down» arrow keys to enter Alphabetical characters.
Press the «Enter» key
Use the «Up» or «Down» arrow keys to select the next operator ID to be edited.
Repeat the same steps through to edit the remaining operator ID's.

4.2. Changing (the User) Password

The use of this password allows the operator to:

- Change the Calibration Coefficients.
- Enter the Special functions menu.
- Change the «Password» itself.

Changing operator

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
2- Chg. Password then press the «Enter» key
Use the «Number» keys to enter any combination of 3 numbers
Press the «Enter» key to accept the password change. Press the «Esc» key to save the previous password.

4.3. Choosing Startup Cycle

The «Startup» cycle is used daily, prior to any normal operation to ensure that detergent from the «Standby» cycle is completely rinsed out of the system.

It includes a Background count which must be verified prior to any analysis of samples. This is necessary to ensure that there are «No» extraneous interferences that may be detected as background noise which will affect the cell count. See Section 3, 1.3. Instrument Startup , page 3-3 for more information regarding Startup.

This Special functions sub-menu will allow the operator to choose between an Automatic or a Manual Startup.

«1- Auto», will automatically run a Startup after the instrument warmup period, once the ABX **Micros 60** has been powered «ON».

«2 - Manual», will allow the operator to Manually press the «Startup» key to initiate the Instrument Startup cycle after instrument warmup.

Choosing Startup cycle

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
3- Startup
Select between:
1- Auto
2- Manual
Press the «Enter» key to accept the change once you have made your selection.

The * indicates the current selection

4.4. Setting Autocleaning frequency

This sub-menu allows the operator to change the cycle frequency of the automatic cleaning cycle which occurs when the cycle number programmed, has been reached.

The Default Cleaning cycle number is factory set to 50 analysis cycles. The user has the option of changing this number from 1 to 99,999.

This Automatic Cleaning cycle involves the use of the solution ABX Miniclean which is an enzymatic cleaner. This solution breaks down protein buildup in the counting chambers and apertures.

If the message «STARTUP CYCLE NOT INITIATED» appears on the display after selecting the mode for startup, press the «Esc» key until you return to the Main Menu then press the «Startup» key to initiate the Startup cycle. This will prevent the «STARTUP CYCLE NOT INITIATED» message from appearing on the printout of any analysis cycle run prior to instrument Startup.

Setting Autocleaning frequency

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
4- Clean freq
Enter the number of the analysis cycles to be run before cleaning
Press the «Enter» key to save or press the «Esc» key to abort.

4.5. Printing Instrument Configuration

This sub-menu allows the operator to print out the internal Instrument settings from all the menus which allow user intervention.

Printing Instrument Configuration

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
5- Print Config
Press the «Enter» key to run the printout of the internal setup

The following information will be printed out as noted:

Date and Time of print request.
Laboratory Limits and Flag values.
Instrument Configuration heading.
Last operator to use Quality Control.
Latest Calibration Lot Number
The most current Calibration Coefficients and last calibrator Target values
The most current RDW calibration coeff.
Most current instrument software version.
Type of analyzer
Open or Closed tube system
Reagent Pack, Yes or No, «Yes» for Reagent pack. «No» for separate Reagents.
Startup mode
Number of parameters that the instrument reports.
Cycle alarm On or Off (audible tone)
Type of Unit Measurements.
Type of printer selected.
Result printout options with or without histograms.
Print out the LMG's, Yes or No.
Print the Laboratory limits with the results, Yes or No.
Type of Host Computer communications.
Barcode reader, Yes or No.
Checksum with barcode reader, Yes or No.
The date format MM-DD-YY or DD-MM-YY
Sample Identification mode
Smart Card reader, Yes or No.
The Memo card option, On or Off.
The Instrument Run mode set for USER and USER «Only»!
The Cycle Start mode, Auto or Manual.
The temperature of the Diluent
The last (5) digits of the Instrument serial number. Complete number is on the back panel of the unit.
The Number of Startup cycles run.
The Number of Standby cycles run.
The number of CBC cycles run.
The number of cycles to be run before the cleaning cycle starts.
The User Password.
The Number of samples to be run during calibration.
Stepper motor steps.
4 operator ID's

Fig.5-2: internal setup printout

4.6. Setting buzzer cycle end

This sub-menu allows the operator to set an audible tone «Beep» when the analysis cycle is complete:

Setting buzzer

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
6- Buzzer yes/no

4.7. Choosing sample identification mode

This sub-menu will allow the operator to select as to how they want to identify their blood samples. 2 options are available in this submenu.

1- **US Mode**: allows the operator to type in up to 13 Alphanumeric characters for a blood sample identification. See Section 3, 3.1. Sample identification modes, page 3-6 for details.

2- **Standard Mode**: allows the operator to enter numbers «Only» from 1 to 99999. See Section 3, 3.1. Sample identification modes, page 3-6 for details.

Choosing sample identification

Main Menu
5- Setup
3- Special
Press the «Enter» key
Enter system default Password <123> (or the one defined by the operator).
Press the «Enter» key
7- ID mode
Select a mode of sample identification
Press the «Enter» key to accept the mode.

Startup results will be printed out in the «US Mode» Only. If «STANDARD Mode» is select for sample identification, the startup results will not be printed out nor will it print out the startup status unless startup has failed.

5. Date and Time

This Setup sub-menu will allow the operator to change time (see "5.1. Change Time , page 15"), date format (see "5.2. Change the Date Format , page 15"), and date (see "5.3. Change Date , page 15") on the instrument to accommodate different time zones and geographical locations when needed.

5.1. Change Time

Changing time

Main Menu
5- Setup
4- Date and Time
1- Chg. Time
Enter the Hours (set for 24 hr.) then press the Decimal (.) key.
Now enter the Minutes.
Press the «Enter» key to save.

5.2. Change the Date Format

This sub-menu will allow the operator to change to format of the date according the Country's specifications.

Changing date format

Main Menu
5- Setup
4- Date and Time
2- Date Format
Select one of the 4 formats below
1- Month, Day, Year (MM-DD-YY)
2- Day, Month, Year (DD-MM-YY)
3- Year, Month, Day (YY-MM-DD)
4- Year, Day, Month (YY-DD-MM)
Press the «Enter» key to accept that specific date format.

5.3. Change Date

This sub-menu allows the operator to change the actual date once the correct format has been selected.

Changing date

Main Menu
5- Setup
4- Date and Time
3- Chg. Date
Enter the first 2 numbers then press the Decimal (.) key.
Enter the second 2 numbers then press the decimal (.) key again.
Now enter the last 2 numbers and press the «Enter» key to save the new date
Press the «Esc» key to exit the Date Time Menu.

6. Host Computer Options

The ABX **Micros 60** is capable of transmitting data to an external computer via the RS-232 interface connection, on the back panel of the analyzer.

6.1. Host Communications

4 different Output formats are available:

1- Format ARGOS, No character identifiers

2- Format R&D, No character identifiers

3- Format ABX, with character identifiers

4- TR OFF, Transmission Off.

Setting output format

Main Menu
5- Setup
6- Host options
1- Host Comm.
Select between the 4 above formats
Press the «Enter» key to accept that specific output format.

6.2. Baud Rate

This sub-menu allows the operator to select the rate of transmitted data to the host computer. There are 5 different rates to select from:

1- 300

2- 1200

3- 2400

4- 4800

5- 9600

Setting Baud rate

Main Menu
5- Setup
6- Host options
2- Baud rate.
Select between the 5 above rate
Press the «Enter» key to accept that specific rate.

6.3. Transmission

This sub-menu will allow the operator to send the last sample results in memory to the Host computer as a transmission acceptance verification. This function is mainly used to verify transmission from the ABX Micros 60 to a host computer.

Setting Baud rate

Main Menu
5- Setup
6- Host options
3- Transmission
Press the «Enter» key to send the last sample results to the Host computer.

7. Barcode Setup

This sub-menu will allow the operator to select the types of Barcode labels to be read by the reader. Turning the Checksum «ON» or «OFF» gives the operator this capability once the Barcode reader has been installed correctly.

Setting Barcode

Main Menu
5- Setup
7- Barcode
Press the «Enter» key to access the CHECKSUM Yes or No sub-menu.

8. Memory Card

This menu will allow the operator to have the option of storing Patient samples on a Memory card or having the Memory card function turned «Off». This Memory card option allows the operator to store up to 60 patient results on the card if the instrument has a card reader installed.

Remember, the ABX **Micros 60** will only hold the «last sample analyzed» in the Internal memory.

The Memory Card option will allow the operator to perform the following tasks from the memory card:

- It will allow the operator to turn the memory card function «On or Off» ("8.1. Memo On / Off , page 17")
- Print a list of all the sample Identifications that have been stored on the card ("8.4. Print List , page 19")
- Select one sample result to Print ("8.5. Reprint One result, page 19")
- Select all sample results to Print ("8.6. Reprint All Results (TR. ALL) , page 20")
- To select from a specific number of samples to be printed ("8.7. Reprint From / To (TR. FROM TO) , page 20")
- The ability to erase all the samples stored and re-use the card if necessary ("8.8. Clear Card (Erasing All Results from the Card) , page 21"
- To transmit your results from the memory card to a printer or to a host computer ("8.3. Transmission of Results , page 18")

8.1. Memo On / Off

Turning Memo Card On/off

Main menu
5- Setup
7- Memo Card
1- Memo
Select either:
1- Memo-ON to enable the use of the Memory card for sample results storage
or 2- Memo-OFF to disable the card.
Press the «Enter» key to confirm the selection.

1- If you choose 1- MEMO-ON and are not using the memory card, a message «NO SMART CARD» will appear on the display when you start a sample analysis cycle. You must use a memory card when analyzing samples. If you do not want to use a memory card,

make sure that the Memo card sub-menu is selected for 2 - MEMO-OFF.

2- If the STANDARD ID Mode (see "4.7. Choosing sample identification mode , page 14") was previously selected before turning the memo card function «On», the ID mode will automatically change to US mode

8.2. Running Patient Samples

1- Place the sample beneath the sample probe and press the manual sample bar to start the cycle (or press the «Start» key to start the cycle).

Entering sample identification

Enter the sample identification (Up to 13 Alphanumeric characters).
Use the «Number» keys to enter the numbers directly.
Use the «Up» and «Down» arrow keys to select each alpha character
Press the «Enter» key after each alphabetical selection.

Then the analyzer checks to see if there is a memory card present in the card reader.

If the memory card has not been inserted, a message will appear on the display as indicated: *Error : No smart card ....Insert new card.*

If a wrong card is inserted instead of a memory card, a message will appear on the display as indicated: *Error : Bad smart card ....Insert new card.* Remove the card, insert a memord card and press the Enter key.

If the operator inserts the memory card in the wrong way, a message will appear on the display as indicated: *Error : Bad card insertion....Insert new card.* Remove the memory card, place the chip in the Up position and forward to the point of insertion. Insert the card and press the Enter key.

If the memory card is full, insert a new memory card, and press the «Enter» key or print out all the results of the full card, clear these results from the card, and re-insert the memory card, then press the «Enter» key.

The Memory card can store up to 60 results. When the card is «Full», it is highly suggested to print out «All» the stored results from the card before using a new card or clearing the full card.

8.3. Transmission of Results

This sub-menu allows the operator to select as to where they want the results from the memory card to be transmitted to. Printer or External computer? The Memo functions for both printer and external computer include:

- Print list of sample ID's to Printer or Computer "8.4. Print List , page 19"
- Print one result to Printer or Computer
- Print all results to Printer or Computer
- Print specific numbers of sample results to Printer or Computer.

Choosing transmission mode

Main menu
5- Setup
7- Memo Card
2- Transmission.
Select: 1- Printer in order to transmit the memory card results to the connected printer
or 2- Host comp. in order to send the results to the external host computer via RS232 port
Press the «Enter» key

8.4. Print List

This Memory card sub-menu allows the operator to print out a complete list of all the sample Identification numbers on the card. This Sample Identifictaion list will include the following information:

- MEMO Number in sequence.
- The date of the analysis.
- The Time of the analysis.
- The Sample Identification number entered by the operator.

Printing list

Main menu
5- Setup
7- Memo Card
3- Print List
Press the «Enter» key

PRT. LIST

MEMO	DATE	TIME	NAME
1	07/21/1999	11:45	12
2	07/21/1999	11:47	456
3	07/21/1999	11:48	675
4	07/21/1999	11:53	984
5	07/21/1999	11:55	R456
6	07/21/1999	13:34	ABC123

etc.....

Fig.5-3: Printing list example

8.5. Reprint One result

This Memory card sub-menu allows the operator to select one specific sample results from the card to be printed out. That one sample results will be printed out according to the Results printout options from the RESULTS Menu such as:

- PRINTOUT, With Histograms, Without Histograms, Without RBC Histogram «Only»
- UNITS, Standard, SI, Inter-1, Inter-2

- PRINT LIMITS, Yes or No
- PRINT LMG's, Yes or No

Proceed as follows:

1- Place the Memory card in the reader.

Printing One Result

Main menu
5- Setup
7- Memo Card
4- TR. One
Press the «Enter» key
Enter the MEMO number next to the sample ID number of the sample results to print (the MEMO number must be known previously)
Press the «Enter» key

8.6. Reprint All Results (TR. ALL)

This Memory card sub-menu will allow the operator to select all the results on the card to be printed out.

Verify that you have a sufficient quantity of paper in the printer for this function. Each individual results will be printed out on a separate sheet of paper.

1- Place the Memory card in the reader.

Printing All Results

Main menu
5- Setup
7- Memo Card
5- TR. All
Press the «Enter» key

If you selected «5. TR ALL» by error, remove the memory card from the reader and press the «Esc» key. Wait until the printer has stopped before continuing through the sub-menu.

8.7. Reprint From / To (TR. FROM TO)

This memory card sub-menu will allow the operator to print out a specified group of sample results starting from a specified number and ending with a specified number.

1- Place the Memory card in the reader.

Printing from to

Main menu
5- Setup
7- Memo Card
6- TR. From To
1- Begin and press the «Enter» key
Enter the wished starting Memo Number
Press the «Enter» key
2- End and press the «Enter» key
Enter the Ending Memo Number
Press the «Enter» key
3- Send Result and press the «Enter» key to send the specific group of results to the printer and/or the host computer

The specific group of sample results will now print out individually on separate sheets of paper.

8.8. Clear Card (Erasing All Results from the Card)

This Memory card sub-menu will allow the operator to delete all the Patient sample results from the card.

1- Place the Memory card in the reader.

Erasing All results

Main menu
5- Setup
7- Memo Card
7- Clear Card
Press the «Enter»
Press the «Esc» key until you return to the MAIN MENU.

It is highly recommended to print out all the complete results from the card before performing this function. This clear card function deletes all results, no partial clearing. These results can not be retrieved at any time.

Contents

1. Maintenance 6-2
1.1. Daily Maintenance 6-2
1.1.1. Startup and Standby Cycles 6-2
1.1.2. Automatic Cleaning 6-2
1.1.3. General Cleaning of the Instrument 6-3
1.2. Reagent connections 6-4
1.2.1. Bottle connections 6-4
1.2.2. Alphalyse 360 6-4
1.2.3. Reagent pack connection 6-5
1.2.4. Diluent & Waste connection 6-7
1.2.5. Reagent priming 6-7
1.3. Service Functions 6-8
1.3.1. Menu Service overview 6-8
1.3.2. Cover dismantling 6-8
1.3.3. Backflush 6-9
1.3.4. Drain Chambers 6-10
1.3.5. Prime Reagents 6-10
1.3.6. Concentrated Cleaning 6-11
1.3.7. Mechanical Checks 6-11
1.4. Instrument Cycles 6-13
1.5. Technician Functions 6-13
1.6. Automatic Cleaning 6-13
1.7. Manual Probe Cleaning 6-13
1.7.1. Unblocking the Sample Probe 6-14
1.7.2. Replacing the Sample Probe 6-15
1.8. Extended Concentrated Cleaning 6-15
2. Troubleshooting 6-17
2.1. Overview 6-17
2.2. Problem Identification 6-17
2.2.1. System Operations 6-17
2.2.2. Reagents 6-17
2.2.3. Precision 6-18
2.2.4. Calibration 6-18
2.3. Troubleshooting Parameters 6-18
2.3.1. Problems on all Parameters 6-19
2.3.2. Problems on RBC/PLT parameters only 6-20
2.3.3. Problems on WBC/HGB parameters only 6-21
2.4. Troubleshooting System Operations 6-22
2.5. Troubleshooting Specific ERROR Messages 6-23
3. Menu/Overview 6-24

1. Maintenance

One of the principle factors contributing to accurate and reliable results is a well-maintained instrument. The ABX **Micros 60** is designed to keep this maintenance automatically to a minimum providing that the operator is aware of its schedule. This section of the manual will describe the daily and periodic maintenance procedures.

1.1. Daily Maintenance

These cleaning procedures are required daily to maintain optimum performance of your ABX **Micros 60**.

Failure to perform any of these recommended cleaning procedures can result in decreased reliability of your system. It is important that you monitor your analyzer for the types of specimens that may cause pre-mature cleaning other than routine.

1.1.1. Startup and Standby Cycles

At the beginning of each business day, a Startup cycle must be performed. This can be done either automatically or or manually which ever the system has been set up for (See Section 5, 4.3. Choosing Startup Cycle, page 5-11).

Running manually a Startup cycle

Press the «Startup» key of the front panel

At the end of each business day, a Standby cycle should be performed. Once the Standby cycle is complete you may power off the instrument or leave it in the standby mode overnight.

Running manually a Standby cycle

Press the «Standby» key of the front panel

The Standby mode introduces MINICLEAN into the chambers for the enzymatic cleaning of Protein build-up on the counting chambers and apertures. This Standby cycle is a very important step in daily maintenance.

1.1.2. Automatic Cleaning

This Automatic cleaning cycle is automatically performed when the number of analysis cycles has been reached to initiate the auto-clean cycle. This cleaning frequency cycle can be programmed by the operator according to the workload of the Laboratory (See Section 5, 4.4. Setting Autocleaning frequency , page 5-11).

Running an automatic cleaning

Main menu
4- Service
8- Auto clean
Press the «Enter» key.

1.1.3. General Cleaning of the Instrument

1.1.3.1. External cleaning

The external surfaces of the instrument must be decontaminated considering the biological environment.

- **Never spill liquids on the instrument.**
- **Never use disinfectant product that contains alcohol**
- **Never use solvants or abrasive materials.**
- **Wipe off any trace of blood spillage as soon as possible.**
- **Always disconnect the main electrical supply before cleaning the exterior of the analyzer. Make sure that the instrument is completely dry before re-connecting the electrical power.**

▼ All contaminated surfaces

Slightly wet a sponge with disinfectant product* and wipe the dirty surfaces.

▼ Stainless steel

Slightly wet a sponge with disinfectant product* and wipe the dirty surfaces. Dry with a soft cloth.

* Products having the following microbiological properties:
  - Bactericidal
  - Fungicidal
  - Active on Aspergillus fumigatus
  - Active on Mycobacterium tuberculosis (B.K)
  - Antiviral (VIH, HBV and rotavirus)

Product Example validated by **HORIBA Medical**:
ANIOS detergent disinfectant ; WIP'ANIOS ; ref: 1316.424

Please also refer to the W.H.O (World Health Organization) guidelines: «Laboratory Biosafety Manual, 2nd edition», for further information.

1.1.3.2. Instrument internal cleaning

▼ Concentrated cleaning

Counting chambers and hydraulics parts are decontaminated by using the «Concentrated cleaning» function as described in "1.3.6. Concentrated Cleaning, page 11".

▼ Sampling probe

Sampling probe must be decontaminated as follows:
1- Prepare a solution of Sodium Hypochlorite to 100ml/l.
2- Fill a 5ml tube with this solution.
3- Run 5 analyses on bleach

Please also refer to the W.H.O (World Health Organization) guidelines: «Laboratory Biosafety Manual, 2nd edition», for further information.

1.2. Reagent connections

1.2.1. Bottle connections

Lyse and cleaning reagents are placed inside the reagent compartment (see "Fig.6-1: Reagent bottles, page 4").
Install the reagent straws and the bottle stoppers.
Connect the blue tube to the MINICLEAN bottle and the white tube to the LYSE bottle.
Close the compartment cover.

Fig.6-1: Reagent bottles

1 - When the ABX Micros 60 is set up with the 16 or 18 parameters mode, it is mandatory to use specific LYSE LMG and MINIDIL LMG reagents.
2 - The Diluent container will be located on the bench at the same level than the instrument.

1.2.2. Alphalyse 360

Open the pack pulling the flap A and open the level window B (see "Fig.6-2: Opening, page 5").

Fig.6-2: Opening

Install the Alphalyse 360 as shown on "Fig.6-3: Alphalyse 360 installation, page 5".

Fig.6-3: Alphalyse 360 installation

1.2.3. Reagent pack connection

Remove the reagent output protections, as well as the waste input protection ("Fig.6-4: Protections, page 6").

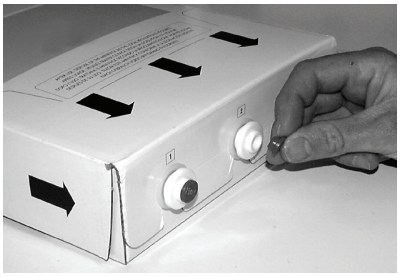


Fig.6-4: Protections

Install the pack into the compartment of the instrument ("Fig.6-5: Pack installation, page 6"). Push the pack down in order to plug correctly the pack on the male connectors.

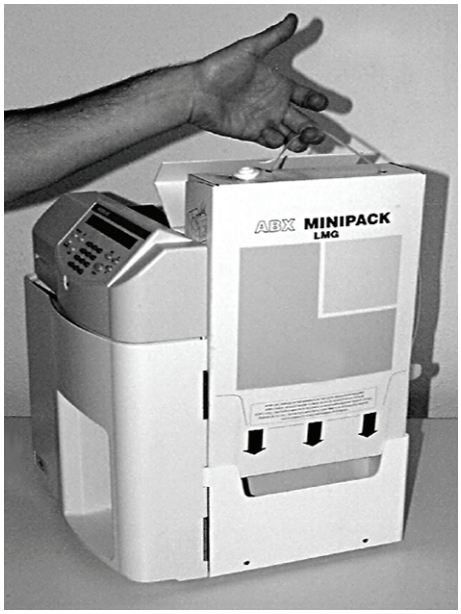


Fig.6-5: Pack installation

The free male connector must be plugged on the pack upper valve in order to receive the waste liquids ("Fig.6-6: Waste connector, page 6").

Fig.6-6: Waste connector

In order to avoid leak problems it is recommended not to unplug several times the same reagent pack.

1.2.4. Diluent & Waste connection

Connect the diluent container using the diluent straw and a 3 x 6 cristal tube (1 meter maximum) on the diluent input located at the bottom of the instrument rear panel.

Connect the waste container using the cristal tube 3 x 6 on the waste output, and place the waste container below the instrument level (under the bench).

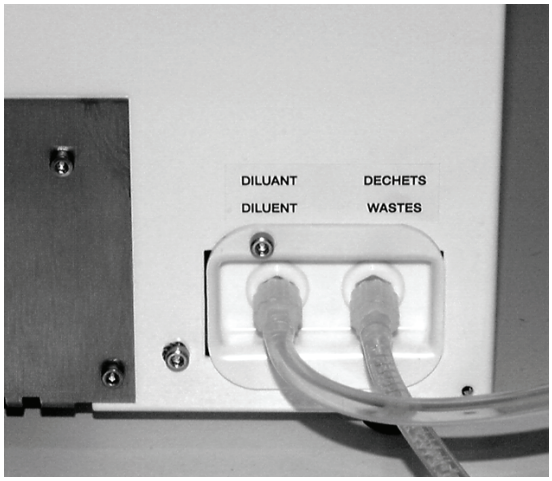


Fig.6-7: Rear connections

Always follow the recommended procedures for waste disposal. Never connect the instrument wastes directly to the laboratory drain pipes.

1.2.5. Reagent priming

1.2.5.1. Bottles and containers set

Step to "1.3.5. Prime Reagents, page 10" to run the priming of the replaced reagent.

1.2.5.2. Reagent pack

Step to "1.3.5. Prime Reagents, page 10" to run the priming after the pack replacement.

It is recommended not to remove the pack several times before the reagents are totally used in order to avoid leak problems.

1.3. Service Functions

Several service functions are available for the operator to clean and check the instrument.

1.3.1. Menu Service overview

Tab.6-1: Menu\Service overview

SERVICE		
1- Backflush		
2- Drain chambers		
3- Prime	Bottle Unit	1- All reagents 2- Diluent 3- Lyse 4- Cleaner
	Pack unit	1- Chg. Pack 2- Capacity 3- Prime Pack
4- Concentrated Cleaning		
5- Mechanic	1- Check sensors 2- Needle U/D 3- Carriage L/R 4- Liquid syringe 5- Pressure syringe 6- Valves 7- Chg. Contrast 8- Park	
6- Cycle #	1- Startup 2- Standby 3- CBC	
7- Technician		
8- Autoclean		

1.3.2. Cover dismantling

Using the key from the installation kit, turn the locker (“Fig.6-8: Door, page 9”) to open the pneumatic protection door.

Fig.6-8: Door

Unscrew the 3 cover fixation screws (A) and loosen the 2 screws (B) under the reagent flap ("Fig.6-9: Cover, page 9").

Remove the cover: pull it backward and lift it up to the rear of the instrument.

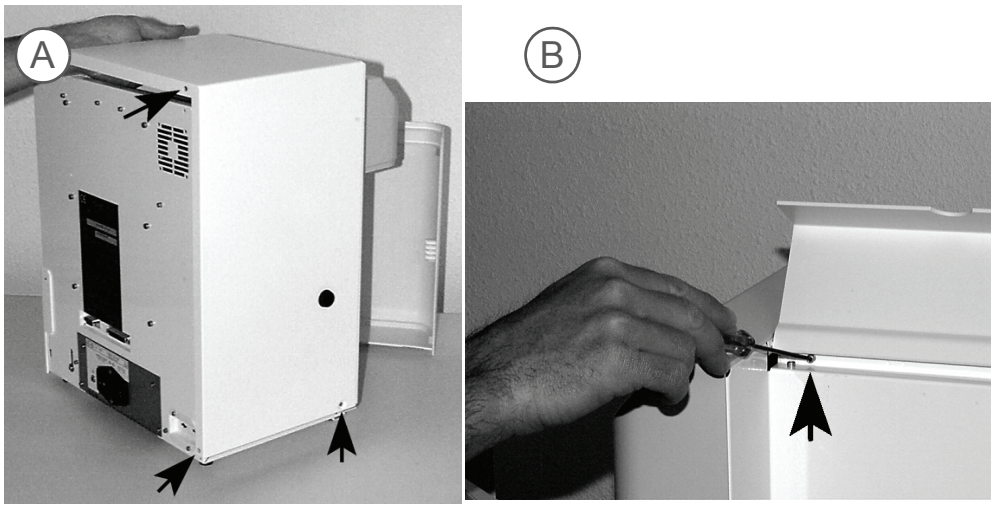


Fig.6-9: Cover

1.3.3. Backflush

This service function will allow the operator to clean the counting chamber apertures in case of blockage.

Performing a backflush cycle

Main menu
4- Service
1- Backflush
Press the «Enter» key

Open the instrument door and verify that liquid is being pulled through the apertures. watch for few micro-bubbles in the count tubing, coming from the count head. When the backflushing starts, verify that liquid is being pushed back through the apertures (watch for few micro-bubbles coming into the chambers through the count head).

If you cannot see any micro-bubbles moving through tubing or in the chambers, the aperture may still be blocked. In this case, perform a Concentrated Cleaning Section 6, 1.3.6. Concentrated Cleaning, page 6-11.

1.3.4. Drain Chambers

This service function will allow the operator to check for proper chamber draining and to maintain some of the parts of the hydraulic manifold as it flushes waste out of the instrument.

Draining chambers
Main menu
4- Service
2- Drain chambers
Press the «Enter» key

Verify the proper draining of the waste through the waste tubing located on the back of the instrument. if it is not flushing waste sufficiently, check the waste tubing connection and verify that there is no blockage or crimping of the tubing. Verify that both the WBC and RBC chambers are draining properly, not slow but fairly rapid. If not, view the troubleshooting Section 6, 2. Troubleshooting, page 6-17.

1.3.5. Prime Reagents

This service function will allow the operator to prime reagents either individually or all at once, depending on the type of system you have (Separate Reagents or Minipack).

1.3.5.1. Bottle unit

Priming reagents
Main menu
4- Service
3- Prime
1- Bottle Unit
Select 1- All Reagents or 2, 3, 4 according to reagent to prime
Press the «Enter» key to start the priming

1.3.5.2. Pack unit

If the current Minipack is low, proceed as described in "1.2.3. Reagent pack connection, page 5" to replace the Minipack and perform the following (step by step instructions will be given on the display when installing a Minipack)

Replacing Pack
Main menu
4- Service
3- Prime
2- Pack unit
1- Change Pack
Press the «Enter» key to start priming

The «2- Pack Unit » menu provides two more functions:
Select «2- Capacity» to display the analyses # left with the current pack
Select «3- Prime Reagents» to run a priming cycle at any time.

When priming reagents or pack, verify that Reagent is being primed. View the Chambers for reagent priming. Verfiy that reagent is coming in and draining out of the chambers when a cycle is initiated. Verify that there are No Air Bubbles in the reagent lines when priming.

1.3.6. Concentrated Cleaning

This service function allows the operator to perform a very strong cleaning of the WBC and RBC counting chambers and apertures.

This service function is used when frequent parameter and/or morphology flags are present on normal patient results.

1- Prepair the following solutions: Minoclair or bleach containing 12% active chlorine.

Running concentrated cleaning

Main menu
4- Service
4- Concentrated Cleaning
Press the «Enter» key and follow the steps that appear on screen

2- Follow the steps that appear on the displays indicated:

3- Open the main cover door of the instrument as described in "1.3.2. Cover dismantling, page 8"

«Pour 3ml of cleaner in the WBC chamber press a key to continue...»

4- Dispense the bleach solution you choose into the WBC chamber (or into the hole on the top of the cover so that it goes into the chamber).

«Pour 3ml of cleaner in the RBC chamber press a key to continue...»

5- Dispense the bleach solution you have chosen into the RBC chamber (or into the hole on the top of the cover so that it goes into the chamber).

After the solution has been added to both chambers, press any key to continue. The cleaning cycle will begin and a cleaning time will be displayed.

This concentrated cleaning cycle involves different cycles, backflush, aspiration, rinsing, which allow a good cleaning of the chambers and apertures. After this procedure is complete, perform a «STARTUP» cycle to verify that the background parameters are within their limits.

Once the Startup cycle has passed, sample analysis may begin.

1.3.7. Mechanical Checks

This service function will allow the operator to move through a sub-menu full of mechanical movements that will allow them to select a specific mechanism for function verification. If the operator suspects a specific mechanical failure, they may then verify it in this menu.

If needed, dismantle the covers as described in "1.3.2. Cover dismantling, page 8"

Running mechanical checks

Main menu
4- Service
5- Mechanic
Select between the 9 below functions:

1- Check Sensors: Needle and Carriage. This allows the operator to check the homing sensors of the sample probe and the sample carriage "1.3.7.1. Check sensors test, page 12"
2- Needle U/D: This allows the operator to check the Up and Down movement of the sample probe.
3- Carriage L/R: This allows the operator to check the Left to Right movement of the sample carriage.
4- Liquid Syringe: This allows the operator to check syringe block that moves Sample, Diluent, and Lyse into the chambers.
5- Pressure Syringe: This allows the operator to check the Vacuum/Waste syringe for complete movement up and down.
6- Valves: This allows the operator to operate all valves on the analyzer in a sequencial order from 1 to 13.
7- Chg. Contrast: This allows the operator to change the contrast of the LCD display.
8- Park: This allows the operator to place the Vacuum/Waste syringe in a position suitable for long term storage of the analyzer.

1.3.7.1. Check sensors test

1- Once you have accessed to the «Check Sensors» Menu as described in "1.3.7. Mechanical Checks, page 11", press the «Enter» key. The display will indicate:

«*Needle Sensor : 0*

Carriage Sensor : 0»

Needle Sensor: Open The Main Door and move the sample needle upwards by the top support bracket. If the sensor is good, it turns from 0 to 1 followed by 10 stars.

Carriage Sensor: With the sample needle in the Up position, move the sample carriage towards the right. If the sensor is good, it turns from 0 to 1 followed by 10 stars as indicated below:

«Needle Sensor : 1 **********

Carriage Sensor : 1 **********»

2- Press any key to exit the function.

If any of these sensors remain at 0 when the mechanism has been moved, call your local **HORIBA Medical Technical Support Representative** for assistance with this issue.

1.3.7.2. LCD Contrast Adjustment

The LCD Contrast can be adjusted as followed:

1- Once you have accessed to the «Chg. Contrast» Menu as described in "1.3.7. Mechanical Checks, page 11", press the «Enter» key.

2- Press the «Up» arrow key to increase the contrast, or press the «Down» arrow key to reduce the contrast.

3- When the contrast is set, press the «Enter» key to accept the change in contrast.

The Contrast Menu can be accessed at any time from any other menu: press and hold the Delete «DEL» key and Period «.» key simultaneously.

1.4. Instrument Cycles

This Service function provides the number of cycles the ABX **Micros 60** has run. This cycle menu will contain 3 cycles to view as indicated:

1 - Startup: the number of Startup cycles that the instrument has ran.

2 - Standby: the number of Standby cycles that the instrument has ran.

3 - CBC: the number of analysis cycles that the instrument has ran.

Viewing cycles number

Main menu
4- Service
6- Cycles
Use the «Up» and «Down» arrows

1.5. Technician Functions

This Service function allows the operator to work with **HORIBA Medical** Technical Support in resolving, checking, and/or adjusting some technical operations on ABX **Micros 60**.

This Service Menu is mainly used by the Engineers to make adjustment in the technical areas of the analyzer.

This Menu can be accessed only by a special password. When troubleshooting your instrument in this area, call your local HORIBA Medical Technical Support Representative for the special password and instructions in this menu area.

1.6. Automatic Cleaning

Provides an automatic Cleaning cycle to run at any time when the operator wishes to clean the instrument.

Running cleaning

Main menu
4- Service
8- Autoclean
Press the «Enter» key

This Auto Clean cycle is a short cycle and may not provide enough cleaning action for Fibrin clots in the apertures and/or chambers. If this is the case, a Concentrated Cleaning is highly recommended (see "1.3.6. Concentrated Cleaning, page 11").

1.7. Manual Probe Cleaning

Concerns:

- Unblocking Sample probe
- Replacing Sample probe

Instrument Response/Problem type

- Low results on all parameters in any analysis mode

- No results on all parameters in any analysis mode
- Possible high backgrounds on Startup

Required Tools

- 5ml or 10ml syringe
- Absorbant paper
- 5 inch small diameter tubing
- Small paper cup

Required Products

ABX MINOCLAIR 0.5L (P/n: 0401005), or bleach containing 12% active chlorine

Intervention time

Approximately 15 minutes

Frequency

- As needed. In case of partially blocked probe
- Bent probe

Specific Kits or Consumable products

Sample probe (p/n: GBC069AS)

1.7.1. Unblocking the Sample Probe

Procedure:

1- Enter the service Menu

Entering service menu
Main menu
4- Service

2- Open the main door of the ABX Micros 60 (see "1.3.2. Cover dismantling, page 8").

3- Now press the «Esc» key to open the tube holder door.

4- Hold the Sample probe mounting bracket on the upper right edge and move the sample probe Downwards until you can see the top of the probe and sample tubing.

5- Remove the tubing from the top of the sample probe.

6- Place the Small paper cup just below the end of the sample probe.

7- Connect a piece of tubing to the tip of the syringe and aspirate the Minoclair.

8- Place the free end of the syringe tubing on the top end of the sample probe and flush the probe. Verify that the solution is flowing directly into the paper cup.

If the Sample probe is free from blockage, the solution stream will appear to be straight. If a blockage is present, the solution stream will appear to be flared and/or at an angle. Flush the probe until the stream is straight.

9- Once the sample probe is free from blockage, carefully remove the paper cup.

10- Re-connect the Sample tubing to the top of the probe so that it is air tight.

11- Hold the Sample probe mounting bracket on the upper right edge and move the sample probe upwards until the tip of the sample probe is about 1 inch below the rinsing block.

12- Press the «Startup» key and verify that the background results are within their limits.

13- Re-run the Quality Controls to verify correct results.

1.7.2. Replacing the Sample Probe

Procedure:

1- Enter the service Menu

Entering service menu
Main menu
4- Service

2- Open the main door of the ABX **Micros 60** (see "1.3.2. Cover dismantling, page 8").

3- Now press the «Esc» key to open the tube holder door.

4- Hold the sample probe mounting bracket on the upper right edge and move the sample probe Downwards until you can see the top of the probe and sample tubing.

5- Remove the tubing from the top of the sample probe.

6- Remove the sample probe Retaining Clip. (Pull the clip out horizontally towards the front of the analyzer).

7- Hold the sample probe mounting bracket on the upper right edge and move the sample Upwards until the top of the probe is just below the front panel.

8- Very carefully pull the sample probe slightly out of its retaining slot.

9- Now hold the sample probe around the retaining collar very carefully lift up the probe so that it is free from the white needle guide.

The sample probe is fragile and may bend if not inserted into the needle guide correctly. Be carefull when placing the probe. Try to maintain a vertical position of the probe when inserting it into the white needle guide.

10- Place the new sample probe in the white needle guide.

11- Place the retaining collar of the probe into its slot.

12- Hold the Sample probe mounting bracket on the upper right edge and move the sample probe upwards until the tip of the sample probe is about 1 inch below the rinsing block.

13- Re-connect the sample tubing to the top of the probe so that it is air tight.

14- Hold the Sample probe mounting bracket on the upper right edge and move the sample probe upwards until the tip of the sample probe is about 1 inch below the rinsing block.

15- Press the «Startup» key and verify that the background results are within their limits.

16- Re-run the Quality Controls to verify correct results.

1.8. Extended Concentrated Cleaning

Concerns

- RBC/PLT Chamber and Aperture cleaning
- WBC/HGB Chamber and Aperture cleaning

Required Tools

5ml or 10ml syringe

Required Products

ABX MINOCLAIR 0.5L (P/n: 0401005), or bleach containing 12% of active chlorine

Intervention Time

Approximately 30 minutes

Specific Kits or Consumable products

None

Procedure

1- Run a backflush sequence

Running Backflush
Main menu
4- Service
1- Backflush

1- Perform a Backflush cycle 2 more times.

2- Drain the chambers

Draining chambers
Main menu
4- Service
2- Drain chambers

3- Open the main door of the ABX Micros 60 (see "1.3.2. Cover dismantling, page 8").

4- Locate the opening on the top of the chamber (shield or not).

5- Fill both chambers with 5ml of the ABX MINOCLAIR.

6- Let the solution set for 10 minutes in the chambers.

7- After 10 minutes, run a Concentrated cleaning as described in "1.3.6. Concentrated Cleaning, page 11".

8- Once the cleaning cycle is complete, perform a Backflush cycle (see "1- Run a backflush sequence, page 16")

9- Perform the Backflush (2) more times.

10- Press the «Esc» key until you return to the Main Menu.

11- Press the «Startup» key to run a startup. Verify that Background results are within their limits.

12- Re-run Quality Control and verify that the results are within the Assay limits listed on the control Assay sheet that comes with the controls.

13- If the problem still persists, repeat steps "1" through "11" again.

14- If the problem still persists after the second cleaning, call your local **HORIBA Medical** Technical Support Representative.

2. Troubleshooting

2.1. Overview

Your ABX **Micros 60** may occasionally require troubleshooting if:

- System operations are faulty.
- The Background count is unacceptably high.
- Your Quality Control values are out-of-range, or patient results are suspicious, e.g.(consistently high RBC counts, or the inability to verify results by manual methods).
- Precision is poor.
- Calibration is drifting.

2.2. Problem Identification

The first step in any troubleshooting session is to identify the source of the system malfunction.

- System operation
- Precision
- Quality Control
- Calibration

These steps hould be carried out in sequence as described below

2.2.1. System Operations

The ABX **Micros 60** software identifies most of the mechanical or hydraulic problems. A Mechanical problem gives an alarm message and stops the current cycle in progress.

A hydraulic problem can be noted by parameter and/or morphology flags. The Waste sensor also gives an error message if a hydraulic problem exists.

- If this is the case, Power OFF then ON the system, and run a Startup.
- If the problem persists during or after startup, identify the source of the malfunction and initiate the appropriate troubleshooting procedures.

2.2.2. Reagents

If your Background count is unacceptable, Quality Control values are out-of-range, or your patient results are suspicious, Reagent deterioration or contamination may be suspected.

- Replace your reagents (see "1.2. Reagent connections, page 4") and perform a Concentrated Cleaning procedure (see "1.3.6. Concentrated Cleaning, page 11").

If the background count is acceptable, but the Quality Control values are still out-of-range or patient results are still suspicious, continue with the indentification procedure. If replacing the reagents performing a concentrated cleaning procedure does not correct the background count problem, call your local **HORIBA Medical** Technical Support Representative for further instructions.

2.2.3. Precision

- ◆In order to verify the precision of the instrument, it is recommended to run a Fresh, Normal Whole blood sample (10) times, mixing between each analysis cycle.
- ◆After all 10 run are complete, calculate the Coefficient of Variation percentage (CV %).
- ◆Compare the CV % results with those listed (See Section 1, 3.3. Precision (Repeatability), page 1-10).

If the precision of any parameter is not within these specifications, identify the out-of-range parameter(s) and initiate appropriate troubleshooting procedures.

Calculation factors for CV% determination

$$\bar{X} = \sum \frac{xi}{n}$$

$$SD = \sqrt{\frac{\sum \langle \bar{X} - Xi \rangle^2}{n-1}}$$

Definitions:

$\bar{X}$ = the calculated Mean

n = the total number of samples

Xi = the individual parameter value

SD = Standard Deviation

$$\textbf{CV \% = (SD x 100)/}\bar{\textbf{X}}$$

- ◆Once the CV%s have been calculated, compare them to the specified limits.

2.2.4. Calibration

If the system seems to be operating properly, fresh uncontaminated reagents are being used, and the precision is within the specifications, the ABX Micros 60 may need calibration (See Section 4, 2. Calibration , page 4-11)

2.3. Troubleshooting Parameters

The procedures described below should be performed whenever the precision of a parameter is not within its CV specifications or the parameter is incorrect or suspicious.

When all parameters are affected, it is necessary to look for a common cause e.g.(Vacuum, pressure,sample aspiration, chamber filling and draining correctly, common reagent pollution, etc....).

When only one parameter is affected, it is necessary to look for a cause in this specific area of analysis. The different tables listed, give the noted problems for the parameter in question, possible cause of the problem, and the necessary user action to correct the problem.

2.3.1. Problems on all Parameters

Tab.6-2:

Problem Noted	Possible Cause	Corrective Action
Startup Failed	Out of Reagent(s)	Check and/or replace reagent(s) if necessary
	Contaminated Reagent(s)	Check and/or replace reagent(s) if necessary
	Possible dirty Apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run startup
No results in analysis	Blocked sample probe	Remove and flush out sample probe as descibed in Section 6, 1.7. Manual Probe Cleaning, page 6-13
	Possible defective Pre-amp on Main Board	Call **HORIBA Medical** technical support for Assistance
Suspicious patient results	Possible dirty Apertures	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible partial blocked sample probe	Remove and flush out sample probe
	Possible leakage from syringe blocks	Check syringe block for leakage and call **HORIBA Medical** Technical support
	Possible Fibrin clot in «T» fitting below WBC chamber	Call **HORIBA Medical** Technical support
Alarm flags on most parameters	Possible dirty Apertures	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run Sample
	Possible Fibrin clot in «T» fitting below WBC chamber	call **HORIBA Medical** Technical support
QC outside acceptable limits	Possible dirty apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe block	Check syringe block for leakage and call **HORIBA Medical** Technical support
	Possible Fibrin clot in «T» fitting below WBC chamber	Call **HORIBA Medical** Technical support
	Poor calibration	Re-calibrate and rerun QC (See Section 4, 2. Calibration , page 4-11)
Poor repeatability	Possible dirty apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe block	Check syringe block for leakage and call **HORIBA Medical** Technical support
	Possible Fibrin clot in «T» fitting below WBC chamber	Call **HORIBA Medical** Technical support
	Poor calibration	Call **HORIBA Medical** Technical support
Poor Chamber drainage	Possible Fibrin clot in «T» fitting below WBC chamber	Call **HORIBA Medical** Technical support
	Possible Vacuum/Waste syringe malfunction	check syringe correct operation as described in "1.3.7. Mechanical Checks, page 11"

2.3.2. Problems on RBC/PLT parameters only

Tab.6-3:

Problem Noted	Possible Cause	Corrective Action
Startup Failed	Possible dirty aperture	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible partial blockage in sample probe	Remove and flush out sample probe as described in Section 6, 1.7. Manual Probe Cleaning, page 6-13
	Possible leakage from syringe block	Check syringe block for leakage and call **HORIBA Medical** Technical support
	Possible contaminated reagent(s)	Check and/or replace reagent(s) if necessary
No results in analysis	Possible dirty apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Has Diluent been delivered correctly into RBC chamber?	Check for diluent delivering into chamber, call **HORIBA Medical** Technical support
Suspicious patient results	Possible dirty Aperture	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and call **HORIBA Medical** Technical support
	Possible dirty chamber	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
QC outside acceptable limits	Possible dirty aperture	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and call **HORIBA Medical** Technical support
	Poor calibration	Re-calibrate and rerun QC (See Section 4, 2. Calibration , page 4-11)
Poor repeatability	Possible dirty apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and call **HORIBA Medical** Technical support
	Possible dirty chamber	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Incorrect sample mixing	Mix sample just before pressing the Manual sample bar for each sample

2.3.3. Problems on WBC/HGB parameters only

Tab.6-4:

Problem Noted	Possible Cause	Corrective Action
Startup Failed	Possible dirty aperture	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible partial blockage in sample probe	Remove and flush out sample probe as described in Section 6, 1.7. Manual Probe Cleaning, page 6-13
	Possible leakage from syringe block	Check syringe block for leakage and call **HORIBA Medical** Technical support
	Possible contaminated reagent(s)	Check and/or replace reagent(s) if necessary
	Possible bad HGB blank reference voltage	Call **HORIBA Medical** Technical support for assistance
No results in analysis	Possible dirty apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Has Diluent been delivered correctly into WBC chamber?	Check for diluent delivering into chamber, call **HORIBA Medical** Technical support
Very high results on WBC/HGB	Possible lyse flow error	Check and/or replace Lyse reagent
	Possible Fibrin clot in «T» fitting below WBC chamber	Call **HORIBA Medical** Technical support
Suspicious patient results	Possible dirty Aperture	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and call **HORIBA Medical** Technical support
	Possible dirty chamber	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
QC outside acceptable limits	Possible dirty aperture	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and call **HORIBA Medical** Technical support
	Poor calibration	Re-calibrate and rerun QC (See Section 4, 2. Calibration , page 4-11)
Poor repeatability	Possible dirty apertures	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Possible leakage from syringe blocks	Check syringe blocks for leakage and call **HORIBA Medical** Technical support
	Possible dirty chamber	Perform a Concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run sample
	Incorrect sample mixing	Mix sample just before pressing the Manual sample bar for each sample

2.4. Troubleshooting System Operations

Tab.6-5:

Problem Noted	Possible Cause	Corrective Action
No Power to the unit	Unit is powered Off and/or power cord is disconnected from power source	Power On unit and/or plug in power cord to power source
	Possible blown power fuses	Call **HORIBA Medical** Technical support for assistance
No Display on LCD screen	Possible disconnection of cable to display	Call **HORIBA Medical** Technical support for instructions on re-connection of cable
	Possible incorrect adjustment on LCD contrast	Press DEL key and Period (.) key simultaneously, re-adjust contrast
Motor Errors on any motor	Possible Motor failure	Check motor operation using "1.3.7. Mechanical Checks, page 11"
	Possible disconnected cable to motor on main board	Remove main cover of the unit, check all connectors, call **HORIBA Medical** Technical support for assistance

2.5. Troubleshooting Specific ERROR Messages

Tab.6-6:

Error message	Corrective Action
Startup Failed	Check and/or replace reagent(s)
	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run startup
	Remove and flush out sample probe Section 6, 1.7. Manual Probe Cleaning, page 6-13. Re-run startup
	Check syringe block for leakage and call **HORIBA Medical** Technical support
	Possible electronic interferences. Call **HORIBA Medical** Technical support for assistance
Startup Failed. HGB reference failed.	Check and/or replace reagent(s)
	Perform a concentrated cleaning "1.3.6. Concentrated Cleaning, page 11", re-run startup
	Possible bad HGB blank reference voltage. Call **HORIBA Medical** Technical support for assistance
Pressure syringe motor error, «Pack» units	For Pack units, remove Waste line from pack, push down on and hold in pack waste valve, push on side of pack to force air out of waste badder. Reconnect waste line.
Pressure syringe motor error, «separate reagent» units	Check for obstruction or restriction of Waste line
	Waste container must be vented
	Possible defective motor, Call **HORIBA Medical** Technical support for assistance.
Liquid syringe motor error	Check syringe block moving smoothly, call **HORIBA Medical** Technical support
	Possible disconnected cable from main board, remove unit cover, check all connectors.
	Possible defective motor, call **HORIBA Medical** Technical support
Carriage motor error	Possible restriction of movement from the chambers to home position, check for restriction
	Possible defective carriage sensor. Proceed as described in "1.3.7.1. Check sensors test, page 12"
	Possible defective motor, call **HORIBA Medical** Technical support
Needle motor error	Possible restriction of movement from the Down position to Up home position, check for restriction
	Possible defective needle sensor.Proceed as described in "1.3.7.1. Check sensors test, page 12"
	Possible defective motor, call **HORIBA Medical** Technical support
Piercing motor error	Possible Micro-switch failure behind Piercing mechanism, check switch contact with applicator stick, call **HORIBA Medical** Technical support for assistance
	Restriction of movement to Up piercing position, check for restriction
	Possible defective piercing motor, call **HORIBA Medical** Technical support

Tab.6-6:

Error message	Corrective Action
No printer error	Printer is Off Line, reset printer (See Section 5, 2.1. Reprint Results , page 5-3)
	Power On and/or reconnect printer to unit (See Section 5, 2.1. Reprint Results , page 5-3)
Printer not selected error	Incorrect printer setup (See Section 5, 2.4. Printer Selection , page 5-5)
Bad Date, Try again! error	Use the Period (.) key between each group of numbers when entering the date. Possible wrong date format, check for the correct date format, re-enter the date. Use the Period(.) key between each group of numbers when entering the date.
Bad Time, Try again! error	Use the Period(.) key between each group of numbers when entering the time.
Startup cycle not initiated	Press the «Startup» key to run a Startup.
Bad Value... MINI : XXX, MAXI : XXX error	◆ Enter correct value between (0 to 99,999) for sample Run # ◆ Out of range Target value in Autocalibration. Enter the correct target value ◆ Out of range run number in Autocalibration. Enter the correct run number between (3 to 11) ◆ Cal coefficient out of range. Enter the coefficient within the range specified in Calibration & Quality Control section

Minimum and Maximum values are displayed with the corresponding error message! Correct your value to be within the specified ranges given. If unable to be within the range specified, call your local HORIBA Medical Technical Support Representative.

3. Menu/Overview

Tab.6-7: Menu «RESULTS»

1- RESULTS
Parameters 1
Pat. ID / Run #
Flags
Parameters 2

Tab.6-8: Menu «QC»

2- QC	
1- Automatic	QC Smart card menu Select OP. lot # Select level (1- Low, 2- Normal, 3- High)
2- Analysis	
3- Print targets	QC Smart card menu Select OP. lot # Select level (1- Low, 2- Normal, 3- High)

Tab.6-8: Menu «QC»

4- Statistics	QC Smart card menu Select OP. lot # Select level (1- Low, 2- Normal, 3- High)
5- Graphs	QC Smart card menu Select OP. lot # Select level (1- Low, 2- Normal, 3- High)

Tab.6-9: Menu «CALIBRATION»

3- CALIBRATION		
1- Autocalibration	Calibrator Smart card menu Select OP. Chg. lot # Chg. Exp. Date Chg. Target Chg. Sample Nb Run Calibration Start Calibration Valid Calibration	
2- Coefficients	1- Calibration coefficients	Password WBC RBC HGB HCT PLT MPV RDW COEFF PDW COEFF
	2- Print Coefficients	

Menu «SERVICE» (see "1.3.1. Menu Service overview, page 8").

Menu «SETUP» (See Section 5, 1. Setup overview, page 5-2).